

**UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS**

INTERNATIONAL UNION OF OPERATING  
ENGINEERS STATIONARY ENGINEERS  
LOCAL 39 HEALTH & WELFARE TRUST  
FUND, individually and on behalf of itself and all  
others similarly situated

Plaintiff,

v.

MEDICIS PHARMACEUTICAL CORP;  
IMPAX LABORATORIES, INC; LUPIN  
LIMITED; LUPIN PHARMACEUTICALS INC.;  
SANDOZ INC; MYLAN, INC.; MATRIX  
LABORATORIES LTD.;  
TEVA PHARMACEUTICAL INDUSTRIES,  
LTD.; TEVA PHARMACEUTICALS USA,  
INC; BARR LABORATORIES INC;  
RANBAXY PHARMACEUTICALS, INC;  
RANBAXY INC.; RANBAXY  
LABORATORIES, LTD.;  
AND VALEANT PHARMACEUTICALS  
INTERNATIONAL, INC.,

Defendants.

Civil Action No.

**CLASS ACTION COMPLAINT**

**JURY TRIAL DEMANDED**

## **CLASS ACTION COMPLAINT**

Plaintiff, International Union of Operating Engineers Stationary Engineers Local 39 Health & Welfare Trust Fund, individually and on behalf of itself and all others similarly situated (“Plaintiff”) brings this class action on behalf of itself and all others similarly situated against Defendants Medicis Pharmaceutical Corp. (“Medicis”), Valeant Pharmaceuticals International, Inc. (“Valeant”) (hereinafter “Medicis” refers to both the Medicis and Valeant Defendants jointly), Teva Pharmaceutical Industries, Ltd., Teva Pharmaceuticals USA, Inc., and Barr Laboratories, Inc. (a wholly owned subsidiary of Teva Pharmaceuticals USA, Inc.) (“Teva”), Impax Laboratories, Inc. (“Impax”), Mylan Laboratories, Inc. and Mylan’s majority owned subsidiary Matrix Laboratories Ltd. (“Mylan”), Lupin Limited and Lupin Pharmaceuticals Inc. (“Lupin”), Ranbaxy Pharmaceuticals, Inc., Ranbaxy Inc., Ranbaxy Laboratories, Ltd. (“Ranbaxy”), Sandoz Inc. (“Sandoz”) (hereinafter, Teva, Impax, Mylan, Lupin, Ranbaxy, and Sandoz, collectively, are the “Generic Defendants,” where Medicis is included, reference will simply be made to “Defendants”). The following allegations are based on personal knowledge, the investigation of counsel and information and belief.

### **I. NATURE OF THE ACTION**

1. This is a civil antitrust action seeking treble damages and other relief arising out of Defendant’ anticompetitive scheme to exclude competition from the market for minocycline hydrochloride extended release tablets, a prescription drug for the treatment of acne marketed by Medicis under the brand name “Solodyn.”

2. As alleged below, Medicis planned and carried out a complex and anticompetitive scheme, undertaken alone and in conjunction with the Generic Defendants, to improperly restrain trade and artificially maintain and abuse Medicis’ monopoly power in the market for

minocycline hydrochloride extended release tablets (aka Solodyn) to the detriment of Plaintiff and the class of end-payor purchasers it seeks to represent (as defined below), causing them to pay overcharges.

3. Solodyn, otherwise known by its chemical name minocycline hydrochloride, is an acne treatment that had become Medicis' highest selling product by mid-2007, about a year after it first gained approval by the Federal Food and Drug Administration (FDA).

4. Solodyn contains, as one of its active ingredients, the antibiotic minocycline. Minocycline was not a novel invention, and as such Solodyn did not qualify for a series of exclusivity provisions within the statutory framework: (1) the five-year marketing exclusivity provided to new molecules, (2) the three-year marketing exclusivity granted to drugs that gain approval using novel clinical studies, and (3) the 30-month automatic stay provided by the Hatch-Waxman Act wherein Medicis would list the patent for minocycline in the Orange Book and trigger the stay simply by filing an infringement suit.

5. Given the importance of Solodyn as defined by Medicis' annual sales, it was important that the drug be insulated from generic competition for as long as possible. A plan was devised by Medicis, comprising various anticompetitive means, to insulate Solodyn from generic competition. This plan is summarized briefly below and expanded upon, *passim*.

6. Medicis' plan to stop generic entry into the relevant market began in December of 2007 when generic manufacturer Impax filed an Abbreviated New Drug Application (an "ANDA") which sought approval to market a generic version of Solodyn. Within this application Impax alleged that the patent at issue, U.S. Patent No. 5,908,838 (hereinafter the "838 Patent"), was invalid and/or unenforceable. Specifically, Impax alleged within the framework of the patent litigation that the '838 Patent was invalid because Medicis withheld

relevant prior art and as such any attempt by Medicis to enforce the patent would have been objectively baseless and “sham litigation” in terms of antitrust laws.

7. During the time Impax’s patent litigation was pending, Medicis began their anticompetitive scheme to thwart generic entry by filing a baseless, “sham” citizen petition with the FDA with the sole intent to delay Impax’s entry into the market. The petition at issue asked the FDA to not approve any generic formulation of Solodyn without first requiring what is called “in vivo” bioequivalence testing for specific strengths of Solodyn, in this case the 45mg, 90mg, and 135mg formulations.

8. This citizen petition was objectively baseless, a sham, and Medicis could have had no reasonable expectation to succeed on the merits of the request in part because the exact opposite argument was made by Medicis during their own FDA approval process for Solodyn when they successfully requested that in vivo testing of various strengths not be required. The citizen petition was filed solely for the purpose of delaying Impax’s generic counterpart and insulating Medicis from generic competition. The strategy worked, and Impax’s product was delayed until February 3, 2009 when the petition was denied and Impax’s ANDA was approved.

9. The anticompetitive scheme continued on November 28, 2008 when, prior to a court ruling on the validity of the ‘838 Patent, and before the FDA could respond to Medicis’ first citizen petition, Impax and Medicis entered into a settlement agreement (“Impax Exclusion Agreement”). Pursuant to this anticompetitive and unlawful agreement, Impax was paid a sum of at least \$55 million to abandon their patent challenge and remain off the market until no sooner than November 26, 2011.

10. A second citizen petition was filed in response to a change in the Hatch Waxman 30 Month Stay provisions by Medicis, the next step in the ongoing anticompetitive scheme.

Medicis argued that a change in the law allowed them to list the active ingredient in the Orange Book and trigger an automatic 30 month stay that would have kept generic entrants out of the market for at least that timeframe. For a variety of reasons, including the aforementioned deceptive misrepresentations and omissions to the patent office with respect to the initial filing of the '838 Patent, Medicis could have no objectively reasonable basis for the filing of the citizen petition and no reasonable litigant could expect to succeed on the merits of the petition as it was submitted. Like the first citizen petition Medicis filed, this one was for the sole and anticompetitive purpose of delaying generic entry into the marketplace, and it did in fact do so as at least one generic competitor, Teva, had their generic formulation delayed until March 17, 2009. FDA approval of Teva's version of Solodyn and the FDA's denial of Medicis' second citizen petition both occurred on this date.

11. Medicis then took several potential competitors, including Teva, Sandoz and Mylan, and entered into a similar anticompetitive and unlawful agreements as the one effectuated between Medicis and Impax. These additional exclusion payment agreements similarly kept the 45mg, 90mg, and 135mg formulations off the market until no sooner than November 2011. In exchange for their signatures on the agreements, the three potential generic competitors received various payments and forms of quid pro quo, including a series of progressive exclusive periods orchestrated by Medicis (*i.e.* each potential generic entrant would contractually be given a six month period where they were guaranteed to be the only one on the market) and an agreement from Medicis not to market an authorized generic during this time period.

12. Finally, Medicis instituted an anticompetitive strategy to switch its existing customer base to different formulations of Solodyn that would not be "AB-rated" with respect to

the current branded product, making it illegal for a pharmacist when given a prescription for Solodyn in one of the new strengths to substitute to a generic product. The “established strengths” of 45, 90, and 135mgs were switched to “new” versions of Solodyn in 55, 65, 80 105, and 115 mg strengths. There was absolutely no benefit, therapeutic or otherwise, to consumers for this so-called “product hopping.” The only benefit to the switch accrued to Medicis.

13. In July 2011, after utilizing its considerable sales force to promote the “new” Solodyn product, Medicis then halted all shipments of Solodyn in the established strengths. The result was that the market for established strength Solodyn had disappeared by the time a generic entrant could have entered the market.

14. Additionally, once generics were ready to enter the revised market for Solodyn, Medicis utilized the same reverse payment agreements that it used to keep the original formulations off the market. When the 65 and 115mg strength Solodyn product was threatened by Teva, the first-filer, Medicis paid them to stay off the market (which at that time comprised more than 75% of their annual sales) and create a so-called “bottleneck.” As the first filer, Teva had the right to market their generic for a six month period without any other generic entrants. By agreeing not to enter the market, Teva and Medicis created a situation where no one else could, either.

15. Any generic company that sought to fix this artificial bottleneck created by Medicis was dealt with in turn: Ranbaxy, Mylan, and Lupin were all paid to stay out of the market. In addition, Lupin was the first-filer as to the 55mg formulation of Solodyn, and Medicis went ahead and entered into the same agreement with them that they use with Teva, parking another 180-day exclusive period and creating yet another bottleneck in the market.

This Lupin agreement contained a reverse payment of at least \$20 million and contained provisions accounting for a potential, additional \$38 million in payments.

16. This overarching, anticompetitive scheme created by Medicis and instituted by all Defendants substantially delayed the entry of generic Solodyn into the market. But for Defendants' reverse payment and sham filing scheme, generic Solodyn would have been available in established strengths as early as December 2008, the date Impax received FDA approval to launch its generic Solodyn product. The impact Medicis' scheme had on the market cannot be overstated: but for the illegal and anticompetitive conduct, a generic would have been on the market in late 2008, Medicis would have launched its own authorized generic (lowering prices in the process), and most importantly, Medicis would not have been able to create an entire artificial market with its product-hopping to slightly different formulations of the drug. Medicis was able to control the supply and demand of its established products using illegal means and in the process gained substantial monopolistic profits.

17. Plaintiff brings this action as a class action on behalf of all consumers and third-party payors (collectively the "End-Payor Class") in the United States, the District of Columbia and Puerto Rico, who purchased or paid for branded and/or generic Solodyn products, other than for re-sale, since December 2008 (see Class Definition below). Plaintiff seeks a judgment declaring that Medicis' overall scheme is unlawful under Section 2 of the Sherman Act, 15 U.S.C. § 2, and that the Exclusion Payment Agreements between and among the Defendants are unlawful under Section 1 of the Sherman Act, 15 U.S.C. § 1. Plaintiff also seeks an injunction pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26, enjoining the continuation of the anti-competitive conduct. Unless enjoined, Defendants' unlawful conduct will continue unchecked and Plaintiff and the End-Payor Class will continue to bear the financial brunt of Defendants'

antitrust violations. Plaintiff also asserts claims for compensatory and/or treble damages and equitable relief for continuing violations of the State laws enumerated below.

## **II. JURISDICTION AND VENUE**

18. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332(d) because this is a class action in which the aggregate amount in controversy exceeds \$5,000,000 and at least one member of the putative class is a citizen of a state different from that of one of the defendants.

19. This Court also has jurisdiction over this matter pursuant to 15 U.S.C. § 26 and 28 U.S.C. §§ 1331 and 1337 in that Plaintiff brings claims under Section 16 of the Clayton Act, 15 U.S.C. § 26, for injunctive and equitable relief to remedy the Defendants' violations of Sections 1 and 2 of the Sherman Antitrust Act, 15 U.S.C. §§ 1 and 2. The Court has supplemental jurisdiction over Plaintiff's pendent state law claims pursuant to 28 U.S.C. § 1367.

20. Venue is appropriate within this district under Section 12 of the Clayton Act, 15 U.S.C. § 22 and 28 U.S.C. §1391(b) and (c), because Defendant transacts business within this district, and/or has an agent and/or can be found in this district, and the interstate trade and commerce, hereinafter described, is carried out, in substantial part, in this district.

## **III. THE PARTIES**

21. Plaintiff International Union of Operating Engineers Stationary Engineers Local 39 Health & Welfare Trust Fund ("Local 39") is a self-insured health and welfare benefit plan with its principal place of business in 337 Valencia Street, San Francisco, California 94103. Local 39 provides reimbursement to its members for some or all of the purchase price of prescription drugs including Solodyn. Local 39 represents participants who reside in and purchased and/or provided reimbursement for some or all of the purchase price of Solodyn in Arizona, California, Georgia, Indiana, Iowa, Nevada, North Carolina, Pennsylvania, Texas and



Washington. The Fund paid more for than it would have for Solodyn absent Defendants' unlawful anticompetitive conduct to prevent generic entry and was injured as a result thereof.

22. Defendant Medicis Pharmaceutical Corp. (hereinafter "Medicis") is a branded pharmaceutical drug manufacturer incorporated under the laws of the State of Delaware, with its principal place of business at 7720 N. Dobson Road, Scottsdale, AZ. Medicis develops, manufactures, and markets pharmaceutical and related products in the United States.

23. Defendant Impax Laboratories, Inc. ("Impax") is a Delaware corporation with its principal place of business at 30831 Huntwood Avenue, Hayward, California 94544. Impax is in the business of developing, manufacturing, and marketing pharmaceutical products, primarily generic products, in the United States.

24. Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation having its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454. Teva USA is in the business of developing, manufacturing, and marketing pharmaceutical products, primarily generic products, in the United States. Teva Pharmaceuticals USA is a wholly owned subsidiary of Teva Pharmaceutical Industries Ltd.

25. Defendant Teva Pharmaceutical Industries Ltd. is a corporation, headquartered and having a place of business at 5 Basel St., Petach Tikva 49131, Israel, engaged in the development, manufacturing, marketing, and distribution of pharmaceuticals. Through its subsidiaries, a large portion of Teva Pharmaceutical Industries Ltd.'s sales are in the United States, and Teva Pharmaceutical Industries Ltd. has major manufacturing operations in the United States. Teva Pharmaceutical Industries Ltd. is the parent company of Teva Pharmaceuticals USA.

26. Defendant Barr Laboratories, Inc. (“Barr”) is a wholly owned subsidiary of Teva Pharmaceuticals USA, Inc., and is a Delaware corporation with offices located at 400 Chestnut Ridge Road, Woodcliff Lake, New Jersey 07677. Barr is in the business of developing, manufacturing, and marketing pharmaceutical products, primarily generic drugs, in the United States.

27. Defendants Teva USA, Teva Pharmaceutical Industries Ltd., and Barr are referred to collectively as “Teva.”

28. Defendant Mylan Inc. is a generic drug manufacturer incorporated under the laws of the Commonwealth of Pennsylvania, with its principal place of business at 1500 Corporate Drive, Canonsburg, Pennsylvania 15317. Mylan is in the business of developing, manufacturing, and marketing pharmaceutical products, primarily generic products, in the United States.

29. Defendant Matrix Laboratories Ltd. is a majority owned subsidiary of Mylan Inc. with its principal place of business at 1-1-15/1, Alexander Road, Secunderabad 500-003, India. Defendants Mylan and Matrix are hereinafter collectively referred to as “Mylan.”

30. Defendant Lupin Limited, is a business entity organized under the laws of India with its principal place of business at Laxmi Towers, B Wing, Bandra Kurla Complex, Bandra (East), Mumbai, Maharashtra 400 051, India.

31. Defendant Lupin Pharmaceuticals, Inc. is a Virginia corporation with its principal place of business at 111 S. Calvert Street, 21st Floor, Baltimore, Maryland 21202. Lupin Pharmaceuticals, Inc. is in the business of developing, manufacturing, and marketing pharmaceutical products, primarily generic products, in the United States. Defendants Lupin Limited and Lupin Pharmaceuticals are hereinafter collectively referred to as “Lupin.”

32. Defendant Ranbaxy Pharmaceuticals, Inc. is a company organized and existing under the laws of Florida, with its principal place of business at 9431 Florida Mining Blvd. East Jacksonville, Florida. Ranbaxy Pharmaceuticals, Inc. is a wholly-owned subsidiary of Ranbaxy Laboratories, Limited.

33. Defendant Ranbaxy Laboratories is organized and exists under the laws of India, and has as its principle place of business Plot 90, Sector 32, Gurgaon-122001 (Haryana), India.

34. Defendant Ranbaxy, Inc. is a Delaware corporation, having a place of business at 600 College Road East, Suite 2100, Princeton, New Jersey.

35. Defendants Ranbaxy Pharmaceuticals, Inc., Ranbaxy Laboratories Limited, and Ranbaxy, Inc. are referred to collectively as “Ranbaxy.” Ranbaxy is engaged in the worldwide production and distribution of pharmaceuticals, primarily generic products, including in the United States.

36. Defendant Sandoz Inc. (“Sandoz”) is a Colorado corporation with its principal place of business at address at 506 Carnegie Center, Princeton, NJ 08540. Sandoz is in the business of developing, manufacturing, and marketing pharmaceutical products, primarily generic products, in the United States.

37. Defendant Valeant Pharmaceuticals International, Inc. (“Valeant”) is a Canadian corporation with its principal place of business at 2150 St. Elzear Blvd. West, Laval, Quebec Canada H7L 4A8. Valeant’s United States headquarters are located at 700 Route 202/206, Bridgewater, New Jersey 08807. Valeant acquired Medicis in an all-cash transaction in December, 2012. The combined company’s commercial dermatology operations are located in Scottsdale, Arizona and operate under the name Medicis, a division of Valeant, with its dermatology research and development operations in Laval, QC, Scottsdale, AZ and Petaluma,

CA, and corporate support is based in New Jersey. Valeant directly and independently participated in the conduct alleged herein.

38. All of Defendants' actions described in this Complaint are part of, and in furtherance of, the unlawful anticompetitive scheme and illegal restraints of trade alleged herein, and were authorized, ordered, and/or performed by Defendants' various officers, agents, employees, or other representatives while actively engaged in the management of Defendants' affairs, within the course and scope of their duties and employment, and/or with the actual or apparent authority of Defendant.

#### **IV. CLASS ACTION ALLEGATIONS**

39. Plaintiff brings this action on behalf of itself and, under Rules 23(a), (b)(2) and (b)(3) of the Federal Rules of Civil Procedure, as representative of a Class defined as follows:

All persons or entities in the United States and its territories who purchased and/or paid for some or all of the purchase price of Solodyn in any form, for consumption by themselves, their families, or their members, employees, insureds, participants, or beneficiaries, other than for resale, at any time during the period December 2008, through the present and continuing until the anticompetitive effects of Defendants' unlawful conduct cease (the "Class Period"). For purposes of the Class definition, persons or entities "purchased" Solodyn if they paid or reimbursed some or all of the purchase price.

The following persons or entities are excluded from the proposed indirect purchaser class:

- a. Defendants and their respective subsidiaries and affiliates;
- b. All governmental entities (except for government funded employee benefit plans);
- c. All persons or entities who purchased Solodyn for purposes of resale or directly from a Defendant to the extent and solely to the extent of such purpose for resale or as a direct purchase;
- d. Insured individuals covered by plans imposing a flat dollar co-pay that was the same dollar amount for generic as for brand drug purchases;
- e. Fully insured health plans, *i.e.* plans that purchased insurance from another third-party payor covering 100% of the plan's reimbursement

obligations to its members;

f. All judges presiding in this case and all counsel or record.

40. Members of the Class are so numerous that joinder is impracticable. Plaintiff believes the Class numbers in the hundreds of thousands. Further, the Class is readily identifiable from information and records in the possession of Defendants.

41. Plaintiff's claims are typical of the claims of the members of the Class. Plaintiff and all members of the Class were damaged by the same wrongful conduct by Defendants, *i.e.*, they paid artificially inflated prices for BPN/NLX and were deprived of the benefits of competition from less-expensive generic versions of Solodyn Tablets as a result of Defendants' wrongful conduct.

42. Plaintiff will fairly and adequately protect and represent the interests of the Class. Plaintiff's interests are coincident with, and not antagonistic to, those of the Class.

43. Plaintiff is represented by counsel who are experienced and competent in the prosecution of class action antitrust litigation, and have particular experience with class action antitrust litigation in the pharmaceutical industry.

44. Questions of law and fact common to the members of the Class predominate over questions, if any, that may affect only individual Class members because Defendants has acted on grounds generally applicable to the entire Class. Such generally applicable conduct is inherent in Defendants' wrongful conduct.

45. Questions of law and fact common to the Class include:

- a. whether Defendants unlawfully maintained monopoly power through their overarching scheme;
- b. whether Medicis unlawfully maintained monopoly power through its product hopping strategy;

- c. whether Medicis obtained the '838 Patent by deceiving the USPTO and improperly listed the '838 Patent in the FDA's Orange Book;
- d. whether Medicis unlawfully maintained monopoly power through its improper filing of multiple sham and/or fraudulently delayed citizen petitions;
- e. whether Defendants conspired to suppress generic competition to Solodyn;
- f. whether Defendants entered into an unlawful agreements in restraint of trade;
- g. whether, pursuant to the Agreements, the Generic Defendants agreed to delay their entry into the market with generic Solodyn;
- h. whether Medicis' payments to the Generic Defendants pursuant to the Agreements were necessary to yield some pro-competitive benefit that is cognizable and non-pretextual and were for a purpose other than to illegally delay generic entry;
- i. whether the Agreements are illegal under the rule of reason;
- j. whether Medicis' introduction of new strengths of Solodyn were intended to impede generic competition;
- k. whether these agreements created a "bottleneck" and impeded generic competition;
- l. whether Defendants' challenged conduct harmed competition in the market(s) in which Solodyn is sold;
- m. whether direct proof of Defendants' monopoly power is available, and if available, whether it is sufficient to prove Defendants' monopoly power without the need to also define a relevant market;
- n. to the extent a relevant market or markets must be defined, what that definition is or those definitions are;
- o. whether the activities of Defendants as alleged herein have substantially affected interstate and/or intrastate commerce;
- p. whether, and to what extent, Defendants' conduct caused antitrust injury to the business or property of Plaintiff and the members of the Class, and;
- q. the quantum of damages paid by the Class in the aggregate.

46. Class action treatment is a superior method for the fair and efficient adjudication of the controversy in that, among other things, such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, and expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities with a method for obtaining redress on claims that might not be practicable to pursue individually, substantially outweigh any difficulties that may arise in management of this class action.

47. Plaintiff knows of no difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

## **V. FACTUAL ALLEGATIONS**

### **A. The Regulatory Structure Pursuant to Which Brand and Generic Drugs Are Approved**

#### **1. The Hatch-Waxman Framework**

48. Under the Federal Food, Drug and Cosmetics Act (21 U.S.C. §§ 301-392) (“FDC Act”), a manufacturer who creates a new drug must obtain the approval of the Food and Drug Administration (“FDA”) to sell the new drug by filing a New Drug Application (“NDA”). An NDA must include submission of specific data concerning the safety and efficacy of the drug, as well as any information on applicable patents.

49. In 1984, Congress amended the FDC Act with the enactment of the Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984), commonly referred to as the Hatch-Waxman Act.

50. Hatch-Waxman simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need for them to duplicate the clinical studies used to obtain

approval for the brand-name counterpart drug. Instead, based on well-established scientific principles, the FDA provides an expedited scientific review process by which generic manufacturers may file and gain approval for their drugs through the filing of an Abbreviated New Drug Application (“ANDA”).

51. The ANDA relies on the scientific findings of safety and efficacy included by the brand-name drug manufacturer in the original NDA. The ANDA filer, however, must scientifically demonstrate to the FDA that the generic drug it is going to market is just as safe and just as effective as the corresponding brand-name drug through demonstrations of bioequivalence. A demonstration of bioequivalence means that, within certain set parameters of variability, the generic product delivers the same amount of active ingredient into the patient's blood stream for the same amount of time as does the corresponding brand drug. The range of acceptable variability afforded to generic drugs for demonstrating bioequivalence is the same lot-to-lot (*i.e.*, batch-to-batch) range of variability afforded to brand companies when manufacturing their own brand drug.

52. Generally speaking, ANDA filers that demonstrate bioequivalence are seeking to have their generic products deemed to be “AB-rated” to the corresponding brand-name drug, sometimes referred to as the “reference listed drug.” AB-rated generics are those that have been determined by the FDA to be therapeutically equivalent (*i.e.*, bioequivalent) and pharmaceutically equivalent to their brand-name counterparts. Pharmaceutical equivalence means the generic drug and branded reference listed drug have, among other things, the same active ingredient, same strength, same route of administration, and same dosage form. Generic drugs that do not fulfill all of these requirements cannot be deemed to be AB-rated to the targeted reference listed drug.



53. Hatch-Waxman also provides brand-name manufacturers with several means, in addition to traditional patent rights, to obtain legitimate protection from generic competition for set, and specifically limited, periods of time. For example, each approved NDA provides the owner of that drug three (3) years of exclusivity. *See* 21 U.S.C. § 355(j)(5)(F)(iii). For pioneer drugs that are truly new or innovative in that they make use of a never-before-approved chemical entity or moiety – as opposed to an NDA relating to the far more common reformulations or dosage changes for existing drugs – the FDA grants a “New Chemical Entity” (“NCE”) exclusivity period of five (5) years. *See* 21 U.S.C. § 355(j)(5)(F)(ii). Outside of the Hatch-Waxman context, if an NDA drug treats a rare condition, the FDA may grant an additional seven (7) years of Orphan Drug exclusivity during which time no corresponding ANDA drug may be approved or commercialized.

**2. AB-rated Generic Versions of Brand-Name Drugs are Significantly Less Expensive, and Take Significant Sales Directly From the Corresponding Brand-Name Versions**

54. Competition from lower-priced AB-rated generic drugs saves American consumers billions of dollars a year. As set forth *infra*, however, these consumer savings mean lower profits for brand drug companies. It is well-established that when AB-rated generic entry occurs, the brand drug company suffers a rapid and steep decline in sales and profits on its reference listed drug.

55. The threat of AB-rated generic competition thus creates a powerful incentive for brand companies to protect their revenue streams. This incentive can prompt brand companies to create innovative new products or new versions of old products that offer real medical benefits to patients. It may also drive brand companies to seek to obstruct generic drug competition by making changes to existing products that offer patients little or, as here, no therapeutic advantages whatsoever, but are intended to interfere with the normal brand-to-

generic competition contemplated and encouraged by the Hatch-Waxman Act and various state laws.

56. Such tactics, often referred to as “product switching” or “product hopping,” can be an effective, albeit anticompetitive, way to game the regulatory structure that governs the approval and sale of generic drugs, thereby frustrating the efforts of federal and state law designed to promote and facilitate price competition in pharmaceutical markets. As discussed in detail below, a brand company can interfere with the mechanism by which generic drugs compete by making non-therapeutic changes to its branded product, and can effectively prevent generic competition, not because the reformulated product is an improvement over the original version of the product or is preferred by consumers, but simply because it differs in strength, route of administration, or, as here, dosage form.

57. Typically, AB-rated generic versions of brand-name drugs are priced significantly below their brand-name counterparts. Because of the price differentials and other institutional features of the pharmaceutical market, AB-rated generic versions are rapidly and substantially substituted for their more expensive brand-name counterparts. When multiple generic manufacturers enter the market, prices for generic versions of a drug predictably decrease even more significantly because of competition among the generic manufacturers, and the loss of sales volume by the brand-name drug to the corresponding generics is dramatic.

58. An AB rating is particularly significant to a generic manufacturer because, under Hatch-Waxman and most state Drug Product Selection laws (“DPS laws”), pharmacists may (and, in many states, must) substitute an AB-rated generic version of a drug for the brand-name drug without seeking or obtaining permission from the prescribing doctor (unless the prescription is denominated “Dispense as Written,” or “DAW”). Indeed, both Congress and

state legislatures have actively encouraged generic substitution because of their recognition that the economics of the pharmaceutical industry prevent generic manufacturers from simultaneously: (a) engaging in the type of heavy promotion or “detailing” typically done by brand-name manufacturers; and (b) providing the enormous cost savings to purchasers and consumers generated by generic drugs.

59. AB-rated generic competition enables indirect purchasers to: (a) purchase generic versions of brand-name drugs at substantially lower prices; and/or (b) purchase the brand-name drug at reduced prices. However, until generic manufacturers enter the market with an AB-rated generic, there is no bioequivalent generic drug which competes with the brand-name drug and therefore, the brand-name manufacturer can continue to charge supra-competitive prices profitably without losing all or a substantial portion of its brand-name sales.

60. This statutorily mandated process, however, is anticompetitively manipulated when brand-name manufacturers, like Defendants here, introduce a new version of an already-existing drug that is no safer and no more effective than the original version, and switch the market to the “new” version thereby causing the conversion of prescriptions for the original drug to be written for the “new” version. The result is that, by the time generic versions of the original brand drug reach the market, there are few, if any, prescriptions being written for the original brand version and, because there is some slight difference between the generic drug and the “new” brand drug (*e.g.*, different milligram strength, route of administration, or dosage form), automatic substitution of the less-expensive generic for the more-expensive brand prescriptions cannot take place. This leaves the generic manufacturer with a couple of choices, both of which result in significantly higher prices for purchasers: (a) implement its own extensive sales and marketing campaign for its generic drug, which dramatically increases the

price for its product (and, as a practical matter, acts as a barrier to meaningful market entry); or (b) abandon altogether its generic product, meaning no generics are available. This anticompetitive result is only exacerbated when the brand company takes additional steps to delay the market entry of generics while it implements the switch scheme, as Defendants did here.

61. The statutory process is further undermined and manipulated through conduct at issue here by Medicis and the generic defendants, including but not limited to the sham filing of multiple citizen petitions, utilizing anticompetitive and illegal exclusion payments to create bottlenecks in the approval process, by the improper filing of patents with the USPTO to abuse the automatic 30-month statutory stay, and by leveraging the threat of an authorized generic to effectuate anticompetitive agreements.

#### **B. Background and Approval of Solodyn**

62. Solodyn is the brand name, prescription acne drug manufactured and sold by Medicis for the treatment of “inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients age 12 and older.” Non-nodular acne are red blemishes on the surface layer of the skin. Solodyn uses a once daily, minocycline hydrochloride extended release tablet with a unique dissolution rate to treat this form of acne.

63. Solodyn was Medicis’ “flagship” product, representing approximately half of Medicis’ total yearly sales at the height of the product’s popularity. Solodyn was touted as “[t]he #1 dermatology medication by dollars in the world and the #1 most prescribed branded dermatology product in the U.S. by prescriptions and dollars.” Sales in 2011 alone exceeded \$700 million.

64. Minocycline was synthesized semi synthetically from natural tetracycline antibiotics by Lederle Laboratories in 1972, which subsequently marketed it under the brand

name Minocin. Antibiotics like minocycline go after specific bacteria responsible for non-nodular acne.

65. Solodyn's active ingredient is minocycline hydrochloride, a semi-synthetic derivative of tetracycline. Extended-release medications like Solodyn use special coatings or ingredients that control how fast the drugs are released from the pill into the patient's body, allowing the patient to take these medications only once or twice a day, providing convenience to customers using products. According to Medicis, Solodyn is "the only branded oral minocycline approved for once daily dosage in the treatment of inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 12 years of age or older" and "the first and only extended release minocycline with eight FDA-approved dosing strengths."

66. Solodyn differs from other, similar antibiotic products that are prescribed to treat similar conditions and as such those products are not considered AB-rated to Solodyn and cannot be substituted. There is no cross-elasticity of demand between Solodyn and these other treatments, and are not economic substitutes nor interchangeable with Solodyn.

67. Solodyn was approved by the FDA on May 8, 2006 pursuant to NDA No. 50-808, and covered extended release tablets in the 45, 90, and 135mg strengths (the "established" product). Subsequently, the FDA granted approval for Medicis to market and sell additional strengths of Solodyn: 55, 65, 80, 105, and 115mg. FDA approved the 65 and 115mg varieties on July 23, 2009, and the rest on August 7, 2010.

68. Medicis currently has the following six patents which relate to Solodyn:

- a. U.S. Patent No. 5,908,838 (the "'838 Patent") was issued by the United States Patent and Trademark Office on June 1, 1999 to Eugene H. Gans and assigned to Medicis. Medicis asserts that the '838

Patent covers "methods for the treatment of acne" through the "use of oral tetracycline antibiotics." The '838 Patent expires on February 19, 2018;

- b. U.S. Patent No. 7,541,347 (the "'347 Patent") was issued to Medicis on June 2, 2009. Medicis then submitted the '347 Patent for listing in the Orange Book in connection with its Solodyn NDA. Medicis asserts that the '347 Patent relates to the use of the 90mg controlled release oral dosage form of minocycline to treat acne. The '347 Patent expires in 2027;
- c. U.S. Patent No. 7,790,705 (the "'705 Patent") was issued on September 7, 2010. Medicis subsequently submitted the '705 Patent for listing in the Orange Book. Medicis asserts that the '705 patent relates to all strengths of Solodyn and expires in 2025;
- d. U.S. Patent No. 7,919,483 (the "'483 Patent") was issued on April 2, 2011 and was listed in the Orange Book thereafter. Medicis asserts that the '483 Patent "covers methods of using a controlled-release oral dosage form of minocycline to treat acne, including the use of our product SOLODYN in all eight currently available dosage forms." The '483 Patent expires in 2027;
- e. U.S. Patent No. 8,268,804 (the "'804 Patent") was issued on September 8, 2012 and was listed in the Orange Book thereafter. Medicis asserts that the '804 Patent covers a method for the treatment of acne and relates to all strengths of Solodyn. The '804 Patent expires in 2025. The '804 Patent had not yet issued at the time of any of the unlawful conduct alleged herein.

69. The '838, '347, '373, '705, '483, and '804 patents are referred to collectively herein as the "Solodyn Patents" and any reference to the patent suite minus the original '838 Patent will be referred to as "the later patents."

70. At the time Medicis submitted, and the FDA approved, its NDA for Solodyn in the established strengths, Congress had not yet enacted the relevant amendment to the Hatch Waxman Act that would have allowed the '838 Patent to have been listed in the Orange Book. That amendment became effective on October 8, 2008, after which Medicis submitted, on December 3, 2008, the '838 Patent for listing in the Orange Book in connection with its Solodyn NDA. Under clear and unambiguous law, Medicis was not entitled to any 30-month stay under the Hatch-Waxman Act for any ANDAs submitted by generic manufacturers for the Solodyn established strengths before Medicis listed the '838 Patent on December 3, 2008.

71. At the time Medicis filed its first sham citizen petition, instituted sham lawsuits with respect to the '838 Patent, and entered the Exclusion Payment Agreements with Impax and Teva, none of the patents that post-dated the '838 Patent had been issued.

72. Additionally, although the '347 and '373 patents had issued by the time of Medicis' Exclusion Payment Agreements with Sandoz and Mylan, and the '705 and '483 patents had also issued by the time of Medicis' Exclusion Payment Agreement with Lupin, none of those patents would have prevented earlier generic entry. But for the anticompetitive conduct at issue, Medicis would not have prosecuted any of these later patents to issuance, because generic entry would have destroyed Medicis' profit motive.

73. Additionally, the later patents did not carry with them any 30-month stay of FDA approval and would therefore not have prevented generic entry. Each of the patents issued after the '838 Patents is weak, likely to have been adjudicated invalid, and declared unenforceable.

**C. The '838 Patent**

74. The '838 Patent purports to describe a treatment of acne that results in the reduction of certain side effects such as vertigo, dizziness or blurred vision following administration of oral tetracycline antibiotics in a slowly dissolving dosage form. Until June 2009, the '838 Patent was the only patent associated with Solodyn.

75. The '838 Patent was wholly or in large based on data collected from a study done on a previous Medicis product called Dynacin. Dynacin was another acne medication and was sold in the United States from at least 1992 onwards.

76. A 1997 study on Dynacin and its relative incidence of negative side effects when compared to similar products was undertaken by Medicis and its employees and published, with Medicis listed as having funded and created the study.<sup>1</sup>

77. Using the data from the Dynacin Study, Medicis filed the application that eventually issued as the '838 Patent, but in doing so did not tell the USPTO that public use of Dynacin occurred before February 18, 1997, that Dynacin had been sold before February 18, 1997, or that the data that formed the basis for the '838 Patent was entirely based on Dynacin and the prior Dynacin Study.

78. Claim 1 of the '838 Patent as it originally issued describes the alleged invention: "A method of reducing the incidence or severity of vestibular side effects resulting from the treatment of acne by the use of oral tetracycline antibiotic, administering the oral tetracycline antibiotic in a slowly dissolving dosage form."

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<sup>1</sup> "A Comparison of the Side Effects Produced by Vectrin and Dynacin After Normal Dosing," originally published in the 1997 issue of Clinical Acne Reviews.



79. The Dynacin product that Medicis had sold since at least February 18, 1997 was encompassed by this claim, as it was based on research on the very same Dynacin product. Given the breadth of this and other similar claims in the '838 Patent, Medicis, its employees, and/or the prosecuting attorneys knew this to be the case but misrepresented and/or withheld this information from the USPTO with deceptive intent.

80. Filing the '838 Patent triggered the legal duty of candor to the USPTO, including the duty to disclose information material to patentability. "Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section. The duty to disclose information exists with respect to each pending claim until the claim is cancelled or withdrawn from consideration, or the application becomes abandoned." 37 C.P.R. § 1.56(a) (July 1, 1999); Manual of Patent Examining Procedure § 2001 (7th ed. July 1998).

81. This legal duty of candor was not followed by Medicis during the process of obtaining the '838 patent. Data from the Dynacin Study was used and reported within the framework of the '838 Patent, but all reference to the prior art of Dynacin was removed from the data presented in the '838 application. In fact, the only data included within the specification of the '838 Patent came directly from the Dynacin Study, without any explanation that the 1992 Dynacin product was available and on sale before February 18, 1997. Medicis, its employees, and/or the prosecuting attorneys intentionally and deceptively omitted from the '838 patent application and supporting materials any and all references to Dynacin. This critical information was omitted because Medicis understood that the prior public use of Dynacin since at least 1992 would have been a bar to obtaining the '838 Patent.

82. A reasonable examiner would have considered each of these misrepresentations and deliberate omissions material to the patentability of one or more of the claims of the '838 patent. The materiality of the information omitted from the '838 Patent suggests that data was selectively chosen from the Dynacin Study and certain unhelpful information intentionally and fraudulently withheld from the USPTO.

83. Additionally a Request for Reexamination was submitted to the USPTO with respect to the '838 Patent in 2008. During this reexamination period, Medicis altered or revised each and every one of the original '838 Patent claims and added several new claims, illustrating that Medicis knew that the '838 Patent as originally issued was likely invalid, this in addition to the alleged invalidity due to the previous sale of Dynacin from 1992 onwards.

84. With respect to the '838 Patent, Medicis, its employees, and/or the prosecuting attorney made false representations or deliberate omissions of highly material information to the USPTO examiner with the intent to deceive the USPTO. The misrepresented and omitted information would have led the examiner to reject the '838 Patent because such information was material to whether the invention was "in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States," and therefore could be anticipatory prior art to the application that led to the '838 Patent. 35 U.S.C. § 102(b).

85. Medicis continued in litigation involving this fraudulent patent with Impax from January to November of 2008 until Medicis ultimately negotiated an Exclusion Payment Agreement, and then later engaged in additional litigation that involved the '838 Patent with several other generic drug manufacturers. Medicis continued to assert the patent against generic competitors despite knowledge that the '838 Patent was procured by fraud and was invalid and/or unenforceable.

**D. Medicis, Reverse Payments, and “Pay for Delay” Strategies to Exclude Generics**

86. On or about October 5, 2007, Impax submitted to the FDA its ANDA 90-024 seeking to market generic versions of Solodyn in 45mg, 90mg, and 135mg strengths. Because there were no Orange Book-listed patents for Solodyn at the time Impax submitted its ANDA, Impax was not required by Hatch Waxman to notify Medicis of its application to market generic Solodyn via the traditional Paragraph IV certification.

87. According to documents filed in the later declaratory judgment action between the parties, on December 20, 2007 Impax notified Medicis of their generic Solodyn ANDA filing and requested that Medicis provide Impax with a covenant not to sue under the '838 Patent in connection with Impax's ANDA 90-024. Impax informed Medicis that any attempt to enforce the '838 Patent against generic versions of Solodyn would be “clearly improper, since the claims of the '838 patent issued only because the patent examiner was not aware of highly relevant prior art during prosecution of the '838 patent.” Impax further notified Medicis that “[i]f Medicis were to attempt to enforce the '838 patent against IMPAX ... such an effort would be objectively and subjectively baseless and would give rise to potential antitrust liability.”

88. Medicis failed to grant Impax's requested covenant not to sue or to respond to Impax's offer of confidential access. Consequently, on January 15, 2008, Impax filed a complaint for declaratory judgment in the United States District Court for the Northern District of California seeking a declaration that the claims of the '838 Patent are invalid and not infringed by Impax.

89. On March 5, 2008, Medicis moved to dismiss Impax's declaratory judgment complaint, arguing that no justiciable Article III controversy existed. Before the court could decide whether Impax had standing to challenge the '838 Patent, however, Medicis

implemented the next in a series of unlawful tactics which were designed to, and did, delay and impair generics.

### **1. Medicis files its First Citizen Petition**

90. On March 18, 2008, while Medicis' motion to dismiss Impax's declaratory judgment complaint was still pending, Medicis filed a sham citizen petition with the FDA solely to delay approval of Impax's ANDA. The Medicis citizen petition, Number FDA-2008-P-0185, asked FDA not to approve any generic versions of Solodyn without requiring in vivo bioequivalence testing for each strength of Solodyn ("Medicis' Proportionality Citizen Petition"). According to the guidelines as they were written at the time of the filing, in vivo bioequivalence testing was required for the 135mg tablets of Solodyn, but not for 45mg and 90mg tablets as long as those strengths were "proportionally similar" to the 135mg tablets.

91. In its citizen petition, Medicis asked that FDA not approve 45mg and 90mg strengths of any generic Solodyn products on the basis of bioequivalence testing on the 135mg strength. In support, Medicis argued that the 45mg and 90mg strengths of Solodyn *are not dose-proportional* to the 135mg strength and therefore requested that FDA designate 90mg Solodyn as a separate reference-listed drug from the 135mg strength, and that the 90mg be the focus of bioequivalence testing for all strengths other than the 135mg.

92. Medicis' argument was *directly contrary* to the argument it had successfully made to the FDA in order to get approval of its own Solodyn products. Medicis convinced the FDA to approve Medicis' own 45mg and 90mg products on the ground that they *are dose-proportional* to the 135mg strength. Furthermore, Medicis' own in vivo pharmacokinetic studies demonstrated that the different strengths of Solodyn result in dose-proportional exposure. FDA therefore approved Solodyn's label, which states: "A single-dose, four-way crossover study

demonstrated that all strengths of Solodyn tablets (45 mg, 90 mg, 135 mg) exhibited dose-proportional pharmacokinetics.” Also based on this finding of dose-proportional exposure, FDA designated the highest approved strength of Solodyn tablets, 135 mg, as the reference standard against which generic versions of Solodyn must establish in vivo bioequivalence.

93. On February 3, 2009, FDA denied Medicis’ Proportionality Citizen Petition.

94. In denying Medicis’ Proportionality Citizen Petition, FDA found that “none of the[] facts” Medicis asserted were “directly relevant to whether ANDA applicants must separately demonstrate in vivo bioequivalence to Solodyn for multiple strengths.” As a result of Medicis’ own studies and labeling, the FDA concluded there was in fact “dose proportional exposure in vivo,” and reaffirmed its prior finding that “135 mg [Solodyn is] the reference standard against which generic versions of Solodyn must establish in vivo bioequivalence.”

95. Medicis’ petition was objectively baseless and a sham, filed only as an attempt to prevent generic entry into the relevant market and slow down the FDA approval process for Impax’s ANDA. Merely filing a citizen petition, regardless of its merits, delays the FDA’s approval process for an ANDA. Adjudicating even a meritless citizen petition requires FDA to expend its time and resources. Absent Medicis’ citizen petition, FDA would have processed Impax’s ANDA more rapidly and approved it earlier.

96. Also on February 3, 2009, FDA gave final approval to Impax’s ANDA Number 90-024 for generic 45mg, 90mg, and 135mg minocycline hydrochloride extended release tablets. But for the sham citizen petition filed by Medicis, Impax would have received approval of their ANDA prior to this date.

97. Impax, however, did not launch its generic Solodyn products on February 3, 2009 despite receiving FDA approval to do so because prior to that, Impax negotiated an anticompetitive agreement with Medicis to delay Impax's entry into the market for three years.

98. In November 2008, while Impax's appeal from a dismissal of their declaratory action based on lack of jurisdiction (and not the merits of the '838 Patent) and Medicis' baseless Proportionality Citizen Petition were still pending, Medicis and Impax entered into the Medicis/Impax Exclusion Payment Agreement. Pursuant to that Agreement, on or about November 26, 2008, Impax agreed to: (a) drop the appeal of its declaratory judgment action against Medicis; (b) admit that the '838 Patent, plus 297 unissued claims from twelve pending patent applications were valid and enforceable; and (c) admit that its activities in connection with its ANDA 90-024 infringed the 838 Patent. At the time of the unlawful Agreement, neither the parties nor the court had addressed any of the substantive merits of the patent dispute.

99. Under the Medicis/Impax Exclusion Payment Agreement, Impax agreed to delay launching its generic Solodyn products in 45mg, 90mg, and 135mg strengths until the earlier of: (a) November 26, 2011; or (b) the date on which another generic version of Solodyn entered the market. In other words, Impax agreed to delay the launch of its generic Solodyn products until November 26, 2011 unless its right to launch earlier than then was triggered by the market entry of another generic Solodyn product.

100. Medicis agreed to pay Impax tens of millions of dollars as a quid pro quo for Impax's agreement to drop its challenge to the '838 Patent. These payments took various forms:

- a. Medicis paid Impax an "upfront fee" of \$40 million under the guise of a Joint Development Agreement providing for the collaboration and

development of four generic dermatology products and an advanced form of Solodyn;

- b. Medicis was obligated to pay Impax up to \$23 million in milestone payments, of which Medicis has already paid Impax \$15 million;
- c. Medicis would pay Impax royalties on sales of the “new” forms of Solodyn, and Impax will receive 50% of all profits on the generic dermatology products;
- d. Impax could distribute an authorized generic version of the subsequent form of Solodyn for a split of the gross profits.

101. Although Medicis and Impax characterize the payments under the Agreement as “consideration for the collaboration and development of additional dermatology products, and/or for the distribution of an authorized generic version of a subsequent branded Solodyn product,” that characterization is pretextual. The payments from Medicis to Impax were for Impax’s agreement to delay generic competition to Solodyn for three years and Impax, as a result, did in fact delay their marketing of generic 45, 90, and 135mg Solodyn products until November 26, 2011.

## **2. Medicis Improperly Lists Patents in Orange Book, Files Sham Patent Suits**

102. On October 8, 2008, Congress enacted the QI (Qualifying Individual) Program Supplemental Funding Act (Pub. Law No. 110-379) (“QI Act”), which amended the FDCA to add new § 505(v)- “Antibiotic Drugs Submitted Before November 21, 1997”- to create certain Hatch-Waxman provisions for “old” antibiotics. The QI Act includes three transitional provisions, which: (1) require antibiotic drug NDA sponsors to submit to FDA for Orange Book listing information on applicable patents within 60 days of enactment of the QI Act; (2) require

FDA to list those patents in the Orange Book not later than 90 days after the enactment of the QI Act; and (3) create “first applicant” status (for 180-day exclusivity purposes) for each ANDA applicant that not later than 120 days after enactment of the QI Act amends a pending application to contain a Paragraph IV certification to a newly listed antibiotic drug patent.

103. On December 3, 2008, Medicis wrongfully submitted the ’838 Patent for listing in the FDA Orange Book. Although the QI Act made the Orange Book listing provisions of Hatch-Waxman generally applicable to old antibiotics like Solodyn, method-of-use patents are eligible for Orange Book listing only if a claim for patent infringement could reasonably be asserted against a generic manufacturer. No reasonable claim for infringing the ’838 Patent could have been asserted because, as discussed above, the ’838 Patent is invalid and/or unenforceable. Medicis nonetheless submitted the ’838 Patent for listing in the Orange Book as part of its plan to delay generic competition.

104. This improper listing of the ’838 patent resulted in multiple Paragraph IV notifications being received by Medicis in quick succession.

105. On or about December 5, 2008, Medicis received a notice letter from Mylan stating that its subsidiary Matrix had filed ANDA 09-0911 seeking to market generic versions of Solodyn in 45mg, 90mg, and 135mg strengths which contained a Paragraph IV certification that the ’838 Patent was invalid, unenforceable, and/or would not be infringed by Mylan’s generic product. Mylan's subsidiary Matrix had filed its ANDA 09-0911 on September 30, 2008.

106. On or about December 8, 2008, Medicis received a notice letter from Sandoz stating that it had filed ANDA 09-0422 seeking to market generic versions of Solodyn in 45mg, 90mg, and 135mg strengths which contained a Paragraph IV certification that the ’838 Patent



was invalid, unenforceable, and/or would not be infringed by Sandoz's generic product.

Sandoz had filed its ANDA 09-0422 before December 5, 2008.

107. On or about December 23, 2008, Medicis received a notice letter from Barr stating that it had filed ANDA 65-485 seeking to market generic versions of Solodyn in 45mg, 90mg, and 135mg strengths which contained a Paragraph IV certification that the '838 Patent was invalid, unenforceable, and/or would not be infringed by Barr's generic product. Barr had filed its ANDA 65-485 in April 2007.

108. On January 13, 2009, Medicis filed suit against Mylan, Barr/Teva, and Sandoz in the United States District Court for the District of Delaware requesting a finding that the generic manufacturers will infringe the '838 Patent by continuing with the ANDA process. No reasonable litigant could have realistically expected Medicis to succeed on its claims that Mylan, Barr/Teva, Sandoz-or any generic manufacturer-infringed the invalid and unenforceable '838 Patent. Medicis filed and prosecuted the '838 Patent infringement suits discussed herein for the sole purpose of delaying generic competition.

### **3. Medicis Files its Second Citizen Petition**

109. On February 13, 2009, Medicis submitted a second baseless citizen petition to FDA, Number FDA-2009-P-0081-0004, requesting that FDA reject: (a) the ANDAs submitted by Mylan, Barr/Teva, and Sandoz; and (b) any other then-pending ANDA referencing Solodyn for which the applicant made a Paragraph IV certification, and for which Medicis sued for patent infringement within the requisite 45-day period ("Medicis' 30-Month Stay Citizen Petition").

110. Just over one month later, on March 17, 2009, FDA denied Medicis' 30-Month Stay Citizen Petition, ruling that no 30-month stay of FDA approval applied because the '838

Patent was not Orange Book- listed until after the ANDAs were pending before FDA.

According to FDA, Medicis' positions were "not supported by either the plain language of the QI Act or by the regulatory framework for innovator and generic drug products of which the QI Act is a part."

111. Medicis had no objectively reasonable basis for its requests that a 30-month stay should apply to ANDAs submitted before the '838 Patent was listed in the Orange Book, and no reasonable petitioner could have expected to succeed on the merits of Medicis' 30-Month Stay Citizen Petition.

112. FDA approved Teva's generic Solodyn ANDA on March 17, 2009, the same date it denied Medicis' 30-Month Stay Citizen Petition. But for Medicis' second sham citizen petition, Teva would have received final approval to launch its generic Solodyn products in 45mg, 90mg, and 135mg strengths before March 17, 2009.

#### **4. Medicis and the Reverse Payments to Teva, Sandoz, and Mylan**

113. As of January 2009, Teva, Sandoz, and Mylan had filed ANDAs for the 45mg, 90mg, and 135mg strengths of Solodyn, and Medicis expected that FDA would quickly grant approval of those ANDAs-as soon as Spring 2009. Medicis knew that FDA was likely to reject Medicis' 30-Month Stay Citizen Petition that spring and so implemented another tactic to delay and limit generic competition from those manufacturers until November 2011.

114. Calling the agreement a "litigation settlement," Medicis arranged for Teva to sell an approximate 6-month supply (for the entire market) of generic Solodyn free from competition from Sandoz or Mylan, and free from competition from a Medicis authorized generic.

115. Immediately after this six month period where only Teva was authorized to sell the generic product, Medicis then arranged for Sandoz to sell generic Solodyn free from competition from Teva or Mylan, and again free from competition from a Medicis authorized generic.

116. This process was then repeated for the third generic company who had filed an ANDA with respect to Solodyn, Mylan. Medicis entered into an agreement and arranged for Mylan to sell generic Solodyn without competition from other generic companies and/or an authorized generic from Medicis.

117. Medicis was able to use these sequential and non-overlapping artificial periods of exclusivity to preserve most of its monopoly profits, and the generics were able to garner profits during their respective six month periods that would equal or exceed what they would have made had the market for generic Solodyn been allowed to function competitively.

## **5. Medicis and the Teva Reverse Payment Scheme**

118. As noted above, on January 13, 2009, Medicis filed suit against Teva, along with Mylan and Sandoz, in the United States District Court for the District of Delaware, No. 1:09-CV-00033-LPS, alleging that Teva infringed the '838 Patent by submitting to FDA the ANDA for 45mg, 90mg, and 135mg minocycline hydrochloride extended release tablets.

119. On February 9, 2009 Teva answered the complaint, asserting that the '838 Patent is invalid and would not be infringed by its generic Solodyn products, and that Medicis improperly obtained the '838 Patent through inequitable conduct. Teva asserted that Medicis had deliberately omitted all mention of its product, Dynacin, and its own Dynacin Study, during prosecution of the 838 Patent before USPTO.

120. On March 17, 2009, FDA granted Teva final approval to market its generic 45mg, 90mg, and 135mg Solodyn products. Teva commenced shipment of its product immediately after the FDA's approval of the ANDA.

121. On or before March 17, 2009, Medicis and Teva entered the Medicis/Teva Exclusion Payment Agreement, which they subsequently memorialized in part in a written agreement dated March 18, 2009. At the time of the Agreement, neither the parties nor the court had addressed the substantive merits of the suit-beyond the initial complaint and answer.

122. Pursuant to that Agreement, Teva agreed to: (a) admit that the '838 Patent, plus the non-issued claims of twelve pending patent applications, are valid and enforceable; (b) admit that the '838 Patent is infringed by Teva's generic Solodyn products; (c) initially sell only a 6-month supply of its generic Solodyn products; and (d) thereafter delay unrestrained entry of its generic Solodyn products until November 2011, or earlier under certain circumstances.

123. As the quid pro quo for Teva's agreement to drop its challenge to the '838 Patent and thereafter delay unrestrained entry of its generic Solodyn products until November 2011, Medicis agreed to make substantial payments to Teva. The payments took the form of Medicis: (a) granting a license to Teva to sell a 6-month supply of its generic Solodyn products beginning on March 17, 2009; (b) agreeing not to grant a similar license to any other generic manufacturer during the period that Teva was negotiating with its buyers regarding the price and quantity terms for the sale of the limited quantity of its generic Solodyn products; and (c) agreeing not to compete against Teva during this period with Medicis' own authorized generic Solodyn. The intended result of the Agreement was that Teva would have the only generic Solodyn product on the market, and that buyers would know, when negotiating with Teva, that it would have the

only generic Solodyn on the market during that time. The Agreement worked as planned, with Teva selling all of the 6-month supply at a price only slightly less than the branded price.

124. Teva reported that its launch of generic Solodyn was one of those “products launched with U.S. market exclusivity, or with otherwise limited competition” which contributed to Teva’s 2009 operating results.” (Teva 2009 20-k Form)

125. The purpose and effect of Medicis’ payment to Teva was to delay unrestrained generic competition to Solodyn until November 2011 (or earlier under certain circumstances). Absent Teva’s agreement to delay unrestrained entry into the market with generic Solodyn, Medicis would not have (a) agreed to refrain from granting a similar license to any other generic manufacturer during the period that Teva was negotiating price and quantity terms for the sale of the limited quantity of its generic Solodyn products; (b) agreed not to compete against Teva during this period with Medicis’ own authorized generic Solodyn; and/or (c) agreed to the terms that it did. Medicis paid Teva to delay unrestrained market entry of generic Solodyn.

## **6. Medicis and the Sandoz Reverse Payment Scheme**

126. As noted above, on January 13, 2009, Medicis filed suit against Sandoz, along with Mylan and Teva, in the United States District Court for the District of Delaware, No. 1:09-CV-00033-LPS.

127. On February 27, 2009, Sandoz answered and asserted a counterclaim of their own seeking judgment that the ’838 Patent was invalid.

128. On or before August 17, 2009, Medicis and Sandoz entered the Medicis/Sandoz Exclusion Payment Agreement. At the time of the Agreement, neither the

parties nor the court had addressed the substantive merits of the suit-beyond the initial complaint and answer.

129. Pursuant to that Agreement, Sandoz agreed to: (a) admit that the '838 Patent, plus the non-issued claims of twelve pending patent applications, are valid and enforceable; (b) admit that the '838 Patent is infringed; (c) initially sell only a 6-month supply of its generic Solodyn products; and (d) thereafter delay unrestrained entry of its generic Solodyn products until November 2011, or earlier under certain circumstances.

130. As the quid pro quo for the Sandoz agreement to drop its challenge to the '838 Patent and thereafter delay unrestrained entry of its generic Solodyn products until November 2011, Medicis agreed to make substantial payments to Sandoz. The payments took the form of Medicis: (a) granting a license to Sandoz to sell a 6-month supply of its generic Solodyn products beginning on August 17, 2009; (b) agreeing not to grant a similar license to any other generic manufacturer; (c) agreeing not to compete against Sandoz during this period with Medicis' own authorized generic Solodyn, and (d) entering into a pretextual "business partnership agreement."

131. The intended result of the agreement was that Sandoz would have the only generic Solodyn product on the market, and that buyers would know, when negotiating with Sandoz, that it would have the only generic Solodyn on the market during that time. Sandoz was in fact able to sell generic Solodyn at or near the branded price during this time period.

132. The purpose and effect of Medicis' payment to Sandoz was to delay unrestrained generic competition to Solodyn until November 2011 (or earlier under certain circumstances).

## **7. Medicis and the Mylan Reverse Payment Scheme**

133. As mentioned above, Medicis had sued Mylan on January 13, 2009, along with Teva and Sandoz, in the United States District Court for the District of Delaware, No. 1:09-CV-00033-LPS. The following is a short timeline of the relevant proceedings that occurred relative to the Mylan and Medicis reverse payment scheme.

134. On February 3, 2009, Mylan answered the complaint and asserted a counterclaim seeking a declaratory judgment that the '838 Patent was invalid.

135. On March 11, 2010, the USPTO issued a Notice of Intent to Issue a Reexamination Certificate stating that the USPTO had closed the reexamination proceedings and intended to issue a Reexamination Certificate as to claims 3, 4, 12 and 13 (which had been amended by Medicis during the reexamination proceedings), and new claims 19-34.

136. On May 7, 2010, Medicis received a Paragraph IV certification from Mylan stating that its majority owned subsidiary Matrix Laboratories Limited had filed an ANDA, Number 20-1467, with FDA for generic Solodyn in 65mg and 115mg strengths. In this Paragraph IV certification, Mylan alleged that the '838 Patent was invalid, unenforceable, and/or would not be infringed by Mylan's generic product.

137. The USPTO issued the Ex Parte Reexamination Certificate on June 1, 2010.

138. On June 14, 2010, Medicis filed suit against Mylan and Matrix in the United States District Court for the District of Delaware, No. 1:10-cv-00524-JJF-LPS, alleging that Defendants infringed the '838 Patent by submitting their ANDAs for 45mg, 90mg, and 135mg, and 65mg and 115mg generic minocycline hydrochloride extended release tablets, respectively.

139. On July 7, 2010, Medicis and Mylan submitted a stipulated motion to extend time for Mylan to answer Medicis' second complaint against it, in case 1:10-cv-00534-LPS, and to

answer an amended complaint in the first case against it, case 1:09-cv-00033, until August 16, 2010.

140. On July 8, 2010, Medicis filed an amended complaint for patent infringement in case 1:09-cv-00033-LPS against Mylan, alleging that through the filing of its ANDA 90-911 Mylan infringed certain claims of the '838 Patent as set forth in the June 1, 2010 Reexamination Certificate.

141. On July 20, 2010, FDA granted Mylan final approval to market its generic 45mg, 90mg, and 135mg Solodyn products.

142. On or before July 21, 2010, Medicis and Mylan entered into the Medicis/Mylan Exclusion Payment Agreement, which they subsequently memorialized in part in a written agreement dated July 22, 2010. At the time of the Medicis/Mylan Exclusion Payment Agreement, the court had not issued any substantive decisions regarding the merits of Medicis' claims or Mylan's counterclaims.

143. Pursuant to that Agreement, Mylan agreed to: (a) admit that the '838 Patent is valid and enforceable; (b) admit that the '838 Patent is infringed by the products described in Mylan's ANDA 90-911 and ANDA 20-1467; (c) initially sell only a limited supply of its 45mg, 90mg, and 135mg generic Solodyn products; (d) thereafter delay unrestrained entry of those generic Solodyn products until November 2011, or earlier under certain circumstances; and (e) delay launching its generic Solodyn products in 65mg and 115mg strengths until certain undisclosed circumstances occurred (additional details on these in-between dosages can be found *passim*, below).

144. As the quid pro quo for Mylan's agreement to drop its challenge to the '838 Patent and thereafter delay entry of its generic Solodyn products until November 2011, Medicis agreed



to make substantial payments to Mylan. The payments took the form of Medicis: (a) granting a license to Mylan to sell a 6-month supply of its generic Solodyn products beginning on July 22, 2010; (b) agreeing not to grant a similar license to any other generic manufacturer; and (c) agreeing not to compete against Mylan during this period with Medicis' own authorized generic Solodyn. The intended result of the Agreement was that Mylan would have the only generic Solodyn product on the market, and that buyers would know, when negotiating with Mylan, that it would have the only generic Solodyn on the market during that time. The Agreement worked as planned, with Mylan selling all of the 6-month supply at a price only slightly less than the branded price.

145. The purpose and effect of Medicis' payment to Mylan was to delay unrestrained generic competition to Solodyn in 45mg, 90mg, and 135mg strengths until November 2011 (or earlier under certain circumstances) and to delay generic competition to Solodyn in 65mg and 115mg strengths. Medicis paid Mylan to delay unrestrained market entry of generic Solodyn.

#### **8. Medicis Provides Cash Payment to Impax after Authorizing Teva, Sandoz, and Mylan's Entry into the Generic Market**

146. Under the Medicis/Impax Exclusion Payment Agreement, if Medicis authorized another generic manufacturer to sell such generic Solodyn products before Impax's licensed entry date of November 2011, Impax had the right to be notified and immediately launch its product. Medicis breached the agreement when it authorized the limited sales of generic Solodyn by Teva, Sandoz, and Mylan referred to above.

147. Shortly after Teva launched its generic Solodyn products, Impax filed suit on May 19, 2009 against Medicis in the Superior Court of the State of Arizona in and for the County of Maricopa alleging that Medicis authorized Teva's launch of its generic Solodyn products and that such launch triggered Impax's right to enter the market before November 2011 under the

Medicis/Impax Exclusion Payment Agreement. Medicis settled the case by paying Impax substantial consideration, and on June 24, 2009, Impax and Medicis submitted a stipulation for dismissal of Impax's suit with prejudice, which was entered by the court on July 1, 2009.

148. The process repeated itself on July 27, 2010, just days after Medicis authorized the third generic manufacturer (Mylan) to sell a limited supply of its generic Solodyn products. After Impax filed suit and Medicis responded with counterclaims against Impax, each party moved to dismiss the other's claims-but before the court reached any substantive decision on the merits-Medicis and Impax entered a January 21, 2011 settlement of the second Arizona state court action. As in the prior settlement, Medicis again paid substantial consideration to Impax in order to end the litigation.

#### **9. Medicis and their Anticompetitive Product Hop**

149. Medicis realized that the agreements entered into to date with various generic manufacturers was simply delaying the inevitable entry of the generic products, so Medicis decided to shift the market to Solodyn in 55mg, 65mg, 80mg, 105mg, and 115mg strengths (the "new strengths") that did not face imminent generic competition.

150. Understanding that the 45mg, 90mg, and 135mg strengths would soon face generic competition, Medicis, concurrent with its unlawful conduct described above, worked to market Solodyn in new strengths that would not be bioequivalent with the existing 45, 90, and 135 mg products, starting with the 65mg and 115mg strengths, then followed by the 55mg, 80mg, and 105mg strengths. On February 29, 2008, Medicis submitted a supplemental NDA 50-808/S-007 seeking approval to market Solodyn in the 65mg and 115mg strengths. On July 23, 2009, the FDA approved Medicis' application.

151. In August 2010, the FDA also approved a supplemental NDA 50 808/S-013 include the 55mg, 80mg, and 105mg strengths.

152. The only real “benefit” of the new dose strengths was to Medicis; because the expected generic Solodyn products in established strengths would not be “AB-rated” to branded Solodyn in the new strengths, pharmacists could not substitute less-expensive generic Solodyn in one of the established strengths when presented with a prescription for Solodyn in one of the new strengths. Such automatic substitution of less-expensive AB-rated generics at the pharmacy counter is the primary means by which generic competition reduces drug prices. Disrupting this competitive price-depression was Medicis’ impetus for creating the new formulations.

153. The scheme worked. By August 2010, the new 65mg and 115mg strengths accounted for 61.5% of new Solodyn prescriptions and 58.5% of total prescriptions. By May 2011, Medicis announced that “92% of the total prescriptions in SOLODYN, moved over to the five new strengths, and 95% of new prescriptions are being written in the new strengths.”

154. And then, in July 2011, shortly before established generics were scheduled to enter the market, Medicis stopped shipping branded Solodyn in established strengths altogether.

155. Medicis’ draining of Solodyn in established strengths from the distribution channel before generic entry had an anticompetitive purpose and effect. The direct result of this artificial supply disruption was little to no established strength Solodyn available in the marketplace from May 2011 through November 2011, when the generic competition was entering the market. Although Medicis’ sales force made every effort to convert existing sales to the new formulations, to the extent a physician nevertheless wrote a prescription for

established strength Solodyn, Medicis' draining of the distribution channel ensured that there would be no established strength Solodyn available at the pharmacy to fill such a prescription.

156. In shifting demand to the new Solodyn strengths, Medicis knew that these strengths offered no medical, convenience, or other benefits to consumers as compared to the established strengths. The recommended dosage of Solodyn is approximately 1mg/kg taken once daily for twelve weeks.

157. The new Solodyn strengths are no more effective and no safer than Solodyn in established strengths. Any purported "benefit" is pure pretext, contradicted at every turn by Medicis' own statements and scientific data.

158. Particularly telling is Medicis' opposition to a May 9, 2011 Suitability Petition filed by Lachman Consultant Services, Inc. ("Lachman Petition") on behalf of a generic manufacturer that wanted to file an ANDA referencing Medicis' Solodyn NDA for different strengths (70mg and 95mg) than those the FDA had previously approved for the drug. The generic manufacturer proposed to recommend the 70mg and 95mg tablets for patients in two new weight classes, which would arguably create even greater weight-based dosing precision. Medicis opposed the Lachman Petition, arguing to the FDA that the new strengths were no safer or more effective than the currently available strengths--even though the creation of two new weight classes around the 70mg and 95mg doses arguably created even more precise dosing around the recommended approximate 1mg/kg dose. Specifically, Medicis argued that recommending a 70mg dose for patients who were previously recommended to take the 65mg dose, an "otherwise equivalent" product, improperly risked doctor confusion as to safety and effectiveness, notwithstanding the arguable creation of more precise dosing, stating: The agency may find, for example, that singling out for higher doses patients weighing 143-157

and 200-212 lbs. - when an otherwise equivalent product (Solodyn) is currently available in lower doses - may confuse healthcare providers and patients. For example, if a patient weighing 143 lbs., who has consistently taken a 65 mg Solodyn tablet, is now guided by a generic product's labeling to take a 70 mg tablet, healthcare providers and-patients may incorrectly believe that the change is based on postmarketing studies or other clinical evidence. They may also incorrectly conclude that FDA's approved 65 mg Solodyn tablet is somehow less safe or effective for a patient weighing 143 lbs. The risk of such potential confusion is unwarranted. Medicis' Aug. 24, 2011 Suitability Petition Response at 5. In other words, it is of no importance to Medicis that a patient weighing 157 lbs., for example, would be getting 0.99 mg/kg if given a 70mg tablet-almost (if not) exactly the approximate 1mg/kg recommended dose-compared to the 0.92 mg/kg if given a 65mg; the doses are "equivalent." After the FDA granted the suitability petition, Medicis sought reconsideration and a stay of that action, characterizing the enhanced dosing precision created by the two new doses as providing "marginal benefit, if any . . ." Medicis Mar. 7, 2013 Petition for Reconsideration and Stay of Action at 5.

159. Moreover, if Medicis were truly concerned with offering physicians greater weight- based dosing precision, it would not have stopped selling Solodyn in three of the eight approved strengths (a fact Medicis omitted from its Suitability Petition response). Without the 45mg, 90mg, and 135mg dose strengths on the market, the FDA-approved Solodyn labeling offers no guidance to doctors as to which dose strength should be prescribed for patients weighing 99-109 pounds (recommended 45mg dose), 187-212 pounds (recommended 90mg dose), or 277-300 pounds (recommended 135mg dose).

160. Medicis publicly derided such lack of guidance in the product's labeling in its opposition to the Lachman Petition. Medicis argued, *inter alia*, that the "safe and effective use of the 70 and 95 mg strengths cannot be ensured" because the FDA-approved Solodyn label instructed patients to take different tablet strengths than those proposed by the Lachman Petition. Thus, under Medicis' own reasoning, the safe and effective use of Solodyn can no longer be ensured for patients in the 99-109, 187-212, or 277-300 pound ranges, who are recommended in the approved Solodyn label to take the discontinued 45mg, 90mg, and 135mg doses, respectively.

161. Medicis' predatory product change was intended to, and had the effect of, harming generic competition and expanding their own ever-increasing exclusivity window to make monopoly profits. Medicis fully expected that, but for the effect of impairing generic competition, launching Solodyn in the new strengths would cause Medicis to lose sales and revenues, increase its costs, and decrease its efficiency.

162. To the extent it is even permitted to do so, Medicis cannot justify its scheme by pointing to any offsetting consumer benefit. The enormous cost savings offered by generic drugs (and, correspondingly, the anticompetitive harm caused by suppressing generic competition to Solodyn) outweigh any cognizable, non-pretextual pro-competitive justifications Medicis could possibly offer. Any cognizable justifications Medicis could offer for its scheme are, in fact, pretexts. And, whatever justifications Medicis may offer, it did not need to engage in the conduct challenged in this lawsuit to achieve them.

163. As a result of Defendants' unlawful conduct, by the time generic Solodyn became available in November 2011, the prescription base for the established strengths was virtually non-existent. But for this predatory product change, together with Medicis' unlawful

exclusion payment agreements and other anticompetitive conduct, generic Solodyn would have been available in the market long before November 2011 and Medicis would not have launched the new Solodyn strengths or, if it had, it would have made far fewer sales of them.

**10. Medicis Doubles-Down: Provides Reverse Payments to Generic Companies for the New Strengths**

164. Having bought time until November 2011 to switch the market to the new dosage strengths, Medicis next took steps to delay competition with respect to these new dosages.

165. After Medicis' predatory product change and switch strategy, the 65mg and 115mg dose strengths comprised approximately 75% of Solodyn sales.

166. Knowing that Medicis' Solodyn patents were weak, generic manufacturers lined up to get FDA approval to market generic versions of the new strengths. To continue to reap the benefits of anticompetitive scheme, Medicis would need to delay and impair this new competitive threat.

167. Medicis impaired that competition through a two-part strategy: (1) Medicis paid Teva, the first-filer with respect to the 65mg and 115mg strengths, to drop its challenge to the patents, delay entry, and "park" its 180-day exclusivity; and (2) Medicis paid the later-filing generic manufacturers, Ranbaxy, Mylan, and Lupin, not to unplug the bottleneck that Medicis and Teva created.

**11. The Second Medicis Teva Reverse Payment**

On November 20, 2009, Medicis received a Paragraph IV certification indicating that Teva had filed a supplement to its ANDA No. 65-485, seeking permission to market generic Solodyn in 65mg and 115mg strengths.

168. Teva was the first generic manufacturer to file a substantially complete ANDA with respect to the 65mg and 115mg strengths and was potentially entitled to 180- day

exclusivity on the generic 65mg and 115mg strengths as a result. The following is a short timeline of the litigation that resulted.

169. On December 28, 2009, Medicis filed suit against Teva in the United States District Court for the District of Maryland, No. 1:09-cv-03464, alleging that Teva infringed one or more claims of Medicis' '838 Patent by submitting the ANDA.

170. On March 5, 2010, Teva answered the complaint, asserting defenses of non-infringement, invalidity, and unenforceability due to inequitable conduct before the USPTO and unclean hands.

171. On July 9, 2010, Medicis filed an amended complaint, alleging that Teva infringed the '838 Patent as amended pursuant to the June 1, 2010 Ex parte Reexamination Certificate.

172. On September 7, 2010, the USPTO issued the '705 Patent, which was later assigned to Medicis. The FDA listed the '705 Patent in the Orange Book for Solodyn in 45mg, 65mg, 90mg 115mg, and 135mg strengths.

173. On October 18, 2010, Medicis filed a second amended complaint, alleging that Teva infringed one or more claims of the '838 Patent and '705 Patent by its ANDA supplement for 65mg and 115mg generic Solodyn.

174. On November 28, 2010, Teva answered the second amended complaint, asserting defenses of non-infringement, invalidity, and unenforceability due to inequitable conduct before the USPTO and unclean hands with respect to the '838 Patent and defenses of non-infringement and invalidity with respect to the '705 Patent.

175. On or about February 25, 2011, Medicis and Teva entered the Second Medicis/Teva Exclusion Payment Agreement.



176. Pursuant to that Agreement, Teva agreed to: (a) admit that the '838 Patent and '705 Patent are valid and enforceable; (b) admit that the '838 Patent and '705 Patent are infringed by Teva's generic Solodyn 65mg and 115mg products; and (c) delay entry of generic 65mg and 115mg Solodyn products until February 2018, or earlier under certain circumstances.

177. As the quid pro quo for Teva's agreement to drop its challenge to the '838 Patent and '705 Patent and thereafter delay entry of its generic 65mg and 115mg Solodyn products until February 2018, Medicis agreed to make substantial payments to Teva. The payments took various forms, including: (a) agreeing to block other generic manufacturers from entering the market with 65mg or 115mg Solodyn products until 180 days after Teva's scheduled entry in February 2018; and (b) agreeing not to compete against Teva with Medicis' own authorized generic 65mg or 115mg Solodyn products. The intended result of the Agreement was that Teva would have de facto 180-day exclusivity for the generic 65mg and 115mg products regardless of whether it was statutorily entitled to such exclusivity (unless later-filing generics won their patent litigations against Medicis), and that there would be no competition between Teva's products and Medicis' own authorized generic 65mg and 115mg products during the 180 days of exclusivity and beyond.

178. The purpose and effect of Medicis' payments to Teva was to delay generic competition to Solodyn 65mg and 115mg until February 2018 (or earlier under certain circumstances). Absent Teva's agreement to delay entry into the market with generic 65mg and 115mg Solodyn, Medicis would not have: (a) agreed to refrain from granting a license to any other generic manufacturer to enter the market before Teva's scheduled entry in February 2018; (b) agreed not to compete against Teva with Medicis' own authorized generic 65mg and 115mg

Solodyn; and/or (c) agreed to the terms that it did. Medicis paid Teva to delay market entry of generic 65mg and 115mg Solodyn.

179. The Second Medicis/Teva Exclusion Payment Agreement created a bottleneck that impaired later-filing generics' ability to get their 65mg and 115mg products onto the market. Medicis also ensured that none of those later filers would dislodge the bottleneck. Medicis used a favorite tactic-more exclusion payments.

## **12. Medicis and the Ranbaxy Reverse Payment Scheme**

180. Medicis filed suit against Ranbaxy on June 11, 2009 in the United States District Court for the District of Delaware, No. 1:09-CV-00435-JJF alleging infringement of its '838 Patent. The following is a short timeline of the litigation that resulted.

181. On July 1, 2009, Ranbaxy answered the complaint, asserting that the '838 Patent was invalid and would not be infringed by Ranbaxy's generic Solodyn product, and that Medicis' claims were barred by the doctrine of unclean hands and patent misuse due to the aforementioned omission of the Dynacin data in the original patent application.

182. On September 24, 2009, Medicis' suit against Ranbaxy was joined with Medicis' suit against Teva, Sandoz, and Mylan in the same court, No. 1:09-vc-00033-JJF.

183. On January 5, 2010, Medicis received Ranbaxy's Paragraph IV certification stating that Ranbaxy had supplemented its ANDA to include the 45mg and 90mg strengths of Solodyn.

184. On February 16, 2010 Medicis sued Ranbaxy in the United States District Court for the District of Delaware, No. 1:10-CV-00120-JJF, alleging that Ranbaxy infringed one or more claims of Medicis' '838 Patent by submitting to FDA its supplemented ANDA for 45mg and 90mg Solodyn. On April 15, 2010, Medicis received Ranbaxy's Paragraph IV certification

stating that Ranbaxy had supplemented its ANDA to include the 65mg and 115mg strengths of Solodyn.

185. Ranbaxy answered Medicis' complaint on April 16, 2010.

186. On May 4, 2010, Medicis and Ranbaxy formally entered the Medicis/Ranbaxy Exclusion Payment Agreement.

187. Pursuant to the Agreement, Ranbaxy agreed to: (a) admit that the '838 Patent was valid and enforceable and covered Ranbaxy's products under ANDA 91-118; (b) be permanently enjoined from any distribution of generic versions of Solodyn except pursuant to the Agreement; (c) delay launching its generic Solodyn products in the 45mg, 90mg, and 135mg strengths until November 2011, or earlier under certain circumstances; and (d) delay launching its generic Solodyn products in the 65mg and 115mg strengths until after Teva launched its generic versions of those products.

188. As the quid pro quo for Ranbaxy's agreement to drop its challenge to the '838 Patent and delay entry of its 45mg, 90mg, and 135mg generic Solodyn products until November 2011 and its 65mg and 115mg products until after Teva launched its generic versions of those strengths, Medicis paid Ranbaxy. That payment took the form of a license to Ranbaxy to make and sell a "branded proprietary dermatology product currently under development by Ranbaxy ... commencing on the later of August 2011 or upon the sale of such product by Ranbaxy following approval by the FDA."

189. The purpose and effect of the Medicis/Ranbaxy Exclusion Payment Agreement was to: (a) delay generic competition to the 45mg, 90mg, and 135mg Solodyn strengths until November 2011 (or earlier under certain circumstances); (b) delay generic competition to the 65mg and 115mg Solodyn strengths; (c) ensure that Ranbaxy would not obtain a court

decision that would trigger the start of Teva's 180-day exclusivity. Absent Ranbaxy's agreement to delay entry into the market with generic Solodyn, Medicis would not have granted Ranbaxy a license to make and sell Medicis' "branded proprietary dermatology product" that was under development by Ranbaxy, or would not have granted that license on the terms that it did. Medicis paid Ranbaxy for delayed market entry of generic Solodyn.

### **13. Medicis and the Lupin Reverse Payment Scheme**

190. On October 8, 2009, Medicis received a Paragraph IV certification from Lupin giving notice that it had filed ANDA No. 19-424 with FDA for generic Solodyn in 45mg, 90mg, and 135mg strengths.

191. On November 17, 2009, Medicis filed a sham suit against Lupin in the United States District Court for the District of Maryland, No. 1:09-cv-03062. The following is a short timeline of the litigation that resulted.

192. On November 24, 2009, Medicis received a Paragraph IV certification from Lupin giving notice that it had filed an amendment and/or supplement to its ANDA Number 19-424, for 65mg generic Solodyn. Lupin's Paragraph IV certification alleged that the '838 Patent was invalid, unenforceable, and/or would not be infringed by Lupin's generic product.

193. On December 23, 2009, Medicis received a Paragraph IV certification from Lupin giving notice that it had filed an amendment and/or supplement to its ANDA Number 19-424, for 115mg generic Solodyn. Lupin's Paragraph IV certification alleged that the '838 Patent was invalid, unenforceable, and/or would not be infringed by Lupin's generic product.

194. On July 1, 2010, Medicis filed its third amended complaint, alleging that Lupin infringed the '838 Patent as amended pursuant to the June 1, 2010 Ex parte Reexamination Certificate.

195. On September 7, 2010, the USPTO issued the '705 Patent, which was later assigned to Medicis. The FDA listed the '705 Patent in the Orange Book for Solodyn after Medicis submitted information regarding the '705 Patent to the FDA on September 9, 2010 for Solodyn in 45mg, 65mg, 90mg, 115mg, and 135mg strengths.

196. On or about September 17, 2010, Medicis received notice from Lupin stating that its ANDA and supplements were submitted with a Paragraph IV certification that the '705 Patent is not infringed.

197. On October 18, 2010, Medicis filed its fourth amended complaint, alleging that Lupin's proposed generic Solodyn products in 45mg, 65mg, 90mg, 115mg, and 135mg strengths would infringe the '838 and '705 Patents.

198. On December 3, 2010, Medicis received a Paragraph IV certification informing it that Lupin had filed an amendment and/or supplement to ANDA Number 19-424, for 55mg and 80mg generic Solodyn. Lupin's Paragraph IV certification alleged that the '838 Patent was invalid, unenforceable, and/or would not be infringed by Lupin's generic product and that the '705 Patent is not infringed.

199. On January 10, 2011, Medicis filed its fifth amended complaint, alleging that Lupin's 55mg and 80mg generic product would infringe the '838 and '705 Patents. Medicis further alleged that Lupin was the first to file an ANDA with respect to the 55 mg strength.

200. On January 24, 2011, Medicis received a Paragraph IV certification informing it that Lupin had filed an amendment and/or supplement to ANDA Number 19-424, for 105mg generic Solodyn. Lupin's Paragraph IV certification alleged that the '838 Patent was invalid,

unenforceable, and/or would not be infringed by Lupin's generic product and that the '705 Patent was not infringed.

201. On March 2, 2011, Medicis filed its sixth amended complaint, alleging that Lupin's 105mg generic Solodyn product would infringe the '838 and '705 Patents.

202. On July 21, 2011, Medicis and Lupin entered into the Medicis/Lupin Exclusion Payment Agreement. At the time of the Agreement, neither the parties nor the court had addressed the substantive merits of the suit.

203. Pursuant to the Agreement, Lupin agreed to: (a) admit that the '838 and '705 patents (and certain other "patent rights" including other patents and patent applications) are valid, enforceable, and infringed by Lupin's proposed generic Solodyn products; (b) delay launching its generic Solodyn products in 45mg, 90mg, and 135mg strengths until November 26, 2011, or earlier under certain circumstances; (c) delay launching its generic Solodyn products in 65mg and 115mg strengths until February 2018, or earlier under certain circumstances; and (d) delay launching its generic Solodyn products in 55mg, 80mg, and 105mg strengths until February 2019, or earlier under certain circumstances. Notwithstanding the foregoing admissions with respect to Medicis' patent rights, Lupin explicitly retained its right to maintain its Paragraph IV certification, thereby creating an FDA approval bottleneck on the 55mg strength of generic Solodyn.

204. As the quid pro quo for Lupin's agreement to drop its challenge to the '838 and '705 Patents and delay marketing its generic Solodyn products, Medicis agreed to pay Lupin tens of millions of dollars or more. Medicis' payments to Lupin under the Agreement took a variety of forms.

205. Medicis paid Lupin an “upfront fee” of \$20 million under the guise of a Joint Development Agreement providing for the collaboration and development of “multiple novel therapeutic products.”

206. In April 2012, Medicis paid Lupin \$2.5 million in connection with the parties entering into the March 30, 2012 Amended and Restated Joint Development Agreement.

207. Medicis additionally agreed to pay Lupin up to \$35.5 million in milestone payments.

208. Finally, to the extent any products are commercialized under the Agreement, Medicis agreed to pay Lupin royalties on sales of such products.

209. Although Medicis’ payments to Lupin under the Exclusion Payment Agreement are characterized as payments for the collaboration on and development of additional products, that characterization is pretextual. In fact, the payments from Medicis to Lupin were for Lupin’s agreement to delay generic competition. Medicis paid Lupin for delayed market entry of generic Solodyn.

## **VI. EFFECTS ON INTERSTATE AND INTRASTATE COMMERCE**

210. At all material times, Medicis manufactured, promoted, distributed, and sold substantial amounts of Solodyn in a continuous and uninterrupted flow of commerce across state and national lines and throughout the United States.

211. At all material times, Defendants transmitted funds, as well as contracts, invoices and other forms of business communications and transactions, in a continuous and uninterrupted flow of commerce across state and national lines in connection with the sale of Solodyn and/or AB-rated bioequivalents.

212. In furtherance of their efforts to monopolize and restrain competition in the market for Solodyn and its generic equivalents, Defendants employed the United States mails and interstate and international telephone lines, as well as means of interstate and international travel. Defendants' activities were within the flow of and have substantially affected interstate commerce.

213. Defendants' anticompetitive conduct has substantial intrastate effects in that, *inter alia*, retailers within each state are foreclosed from offering less expensive generic Solodyn to end-payors inside each respective state. The foreclosure of generic Solodyn directly impacts and disrupts commerce for end-payors within each state.

## **VII. MARKET POWER AND MARKET DEFINITION**

214. At all relevant times, Medicis had substantial market power, *i.e.*, monopoly power, with respect to minocycline hydrochloride extended release tablets because it had the power to maintain the price of the drug it sold as Solodyn at substantially supracompetitive levels without losing so many sales as to make the supracompetitive price unprofitable.

215. A small but significant, non-transitory price increase above the competitive level for Solodyn by Medicis would not have caused a loss of sales sufficient to make the price increase unprofitable.

216. At competitive price levels, Solodyn does not exhibit significant, positive cross-elasticity of demand with respect to price with any product other than AB-rated generic versions of Solodyn.

217. The differing efficacy, safety, and side effect profiles of different treatments for non-nodular moderate to severe acne play a critical role in doctors' selection of the



most appropriate treatment for a particular patient. The FDA does not consider these various products to be bioequivalent.

218. For clinical reasons, among others, physicians and patients prefer Solodyn to other products designed to treat non-nodular severe to moderate acne. Due to, among other reasons, its once-daily dosing of extended release tablets with a unique dissolution profile that provides an effective dose with reduced side effects, Solodyn is significantly differentiated from all products other than AB-rated generic versions of Solodyn. And as described in detail above, the “price disconnect” very substantially reduces the price elasticity of demand between Solodyn and other products designed to treat non-nodular severe to moderate acne.

219. The existence of other products designed to treat non-nodular severe to moderate acne has not significantly constrained Medicis’ pricing of Solodyn. At all relevant times, Medicis’ price for Solodyn has been at least 60% above its marginal cost of production, and at least 40% above its marginal cost including marketing costs. Medicis has never lowered the price of Solodyn in response to the pricing of other branded products indicated for the treatment of non nodular severe to moderate acne oral contraceptives (or the generic versions of those other products).

220. Medicis needed to control only Solodyn and its AB-rated generic equivalents, and no other products, in order to maintain the price of Solodyn profitably at substantially supracompetitive prices. Only the market entry of a competing, AB-rated generic version of Solodyn would render Medicis unable to profitably maintain substantially supracompetitive prices for Solodyn.

221. Medicis knew that entry of a generic version of Solodyn would be a uniquely significant market event. The entry of other products indicated to treat non-nodular severe to

moderate acne (or generic versions of those other brands) did not take substantial sales from Solodyn or cause Medicis to lower its price. But Medicis predicted that entry of generic Solodyn would immediately cause branded Solodyn to lose well more than half of its unit sales. Likewise, the Generic Defendants estimated that their generic versions of Solodyn would take essentially all of their sales from branded Solodyn and few if any sales from other branded products indicated to treat non-nodular severe to moderate acne.

222. Defendants predicted that the competitive impact of a generic version on branded Solodyn would be substantial. Among other things, all Defendants predicted that entry of generic Solodyn would deliver hundreds of millions of dollars of savings to consumers.

223. At all relevant times, Medicis has sold Solodyn at prices well in excess of marginal costs, and in excess of the competitive price, and enjoyed high profit margins.

224. Medicis had, and exercised, the power to exclude and restrict competition to Solodyn and its AB-rated bioequivalents.

225. Medicis, at all relevant times, enjoyed high barriers to entry with respect to competition in the relevant product market due to patent and other regulatory protections and high costs of entry and expansion.

226. To the extent that Plaintiff is legally required to prove substantial market power circumstantially by first defining a relevant product market, Plaintiff alleges that the relevant product market is minocycline hydrochloride extended release tablets or narrower markets contained therein. During the relevant time, Medicis has been able to profitably maintain the price of minocycline hydrochloride extended release tablets substantially above competitive levels.

227. The relevant geographic market is the United States and its territories.

228. At all relevant times, until the entry of AB-rated generic competition, Medicis' market share in the relevant market was and remains 100% or nearly 100%, implying a substantial amount of market power.

### **VIII. ANTITRUST IMPACT**

229. During the relevant period, Plaintiff and/or members of the Class purchased substantial amounts of brand Solodyn indirectly from Defendants and/or purchased substantial amounts of AB-rated bioequivalent generic Solodyn indirectly from Defendants or others. As a result of Defendants' illegal conduct, members of the End-Payor Class were compelled to pay, and did pay, artificially inflated prices for their minocycline hydrochloride extended release tablets requirements. Those prices were substantially greater than those that members of the Class would have paid absent the illegal conduct alleged herein, because: (1) the price of brand Solodyn was artificially inflated by Defendants' illegal conduct; (2) Class members were deprived of the opportunity to purchase lower-priced generic versions of Solodyn; and/or (3) the price of AB-rated Solodyn generic was artificially inflated by Defendants' illegal conduct.

230. As a consequence, Plaintiff and members of the Class have sustained substantial losses and damage to their business and property in the form of overcharges. The full amount and forms and components of such damages will be calculated after discovery and upon proof at trial.

231. Overcharges at a higher level of distribution generally result in higher prices at every level below.

232. Wholesalers and retailers passed on the inflated prices of Solodyn and AB-rated generic Solodyn to the End-Payors defined herein.

233. Defendants' anticompetitive conduct enabled them to indirectly charge consumers and third-party payors prices in excess of what Defendants otherwise would have been able to charge absent Defendants' anticompetitive conduct.

234. The prices were inflated as a direct and foreseeable result of Defendants' anticompetitive conduct.

235. The inflated prices the End-Payor Class paid are traceable to, and the foreseeable result of, the overcharges by Defendants.

## **IX. CLAIMS FOR RELIEF**

### **COUNT ONE: MONOPOLIZATION UNDER STATE LAW** **(Alleged against Defendant Medicis)**

236. Plaintiff refers to, and incorporates herein, each allegation in the preceding paragraphs.

237. At all relevant times, Defendants possessed monopoly power in the relevant market.

238. Defendants manufactured the various formulations of Solodyn described herein. Defendants, *inter alia*, marketed and sold those various versions of Solodyn in the United States. During the relevant period, Defendants willfully and unlawfully maintained its monopoly power by engaging in exclusionary conduct that discouraged rather than encouraged competition on the merits. As explained in detail above, Defendants engaged in an exclusionary scheme that included, *inter alia*, each of the following (at various times):

- a. obtaining the '838 Patent by making deliberate misrepresentations and omissions to the Patent and Trademark Office;
- b. improperly submitting the invalid and/or unenforceable '838 Patent to the FDA for Orange Book listing;

- c. enforcing the '838 Patent in bad faith against its prospective generic competitors by filing objectively baseless sham patent suits solely to delay generic competition to Solodyn;
- d. filing two objectively baseless sham citizen petitions with FDA solely to delay generic competition to Solodyn;
- e. entering multiple Exclusion Payment Agreements with, between, and among its prospective generic competitors relating to Solodyn in established strengths;
- f. engaging in a predatory product hop from Solodyn in established strengths to Solodyn in the "new" dosage strengths; and
- g. entering multiple Exclusion Payment Agreements with, between, and among its prospective generic competitors relating to Solodyn in the "new" dosage strengths.

239. The goal, purpose and/or effect of Defendants' scheme was to prevent, delay, and/or minimize the success of the entry of generic competitors which would have sold generic Solodyn in the United States at prices significantly below Defendants' prices for Solodyn, which would have effectively caused the average market price of Solodyn to decline dramatically.

240. The goal, purpose, and effect of Medicis' scheme was to delay and impair the sale of generic Solodyn products in the United States at prices significantly below Medicis' prices for Solodyn, thereby effectively preventing the average market price of extended-release minocycline hydrochloride products from declining dramatically.

241. Through the overarching anticompetitive scheme, as alleged extensively above, Medicis willfully maintained its monopoly power in the relevant market by means of restrictive or exclusionary conduct, rather than by means of greater business acumen, in order to exclude competition for Solodyn.

242. Plaintiff and members of the Class have been injured in their business or property by reason of Medicis' antitrust violations alleged in this Claim. Their injuries consist of: (1) being denied the opportunity to purchase lower-priced generic Solodyn products; and (2) paying

higher prices for Solodyn products than they would have paid in the absence of Medicis' conduct. These injuries are of the type the laws of the above States, the District of Columbia, and Puerto Rico were designed to prevent, and flow from that which makes Defendants' conduct unlawful.

243. Plaintiff and the End-Payor Class seek damages and multiple damages as permitted by law for their injuries by Defendants' violations of the following state antitrust laws:

- a. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Arizona Rev. Stat. §§ 44- 1402, *et seq.*, with respect to purchases of Solodyn in Arizona by members of the Class.
- b. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Cal. Bus. & Prof. Code §§ 16700, *et seq.*, with respect to purchases of Solodyn in California by members of the Class.
- c. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of D.C. Code §§ 28-4503, *et seq.*, with respect to purchases of Solodyn in the District of Columbia by members of the Class.
- d. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Fla. Stat. §§ 501.201, *et seq.*, with respect to purchases of Solodyn in Florida by members of the Class.
- e. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Hawaii Code §480, *et seq.*, with respect to purchases of Solodyn Tablets in Hawaii by members of the Indirect Purchaser Class.
- f. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Iowa Code §§ 553, *et seq.*, with respect to purchases of Solodyn in Iowa by members of the Class.
- g. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Kan. Stat. Ann. §§ 50-101, *et seq.*, with respect to purchases of Solodyn in Kansas by members of the Class.
- h. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Me. Rev. Stat. Ann. 10, §§ 1102, *et*

*seq.*, with respect to purchases of Solodyn in Maine by members of the Class.

- i. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Mass. Ann. Laws. Ch. 93A, *et seq.*, with respect to purchases of Solodyn in Massachusetts by members of the Class.
- j. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Mich. Comp. Laws Ann. §§ 445.772, *et seq.*, with respect to purchases of Solodyn in Michigan by members of the Class.
- k. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Minn. Stat. §§ 325D.52, *et seq.*, and Minn. Stat. § 8.31, *et seq.*, with respect to purchases of Solodyn in Minnesota by members of the Class.
- l. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Miss. Code Ann. §§ 75-21- 3, *et seq.*, with respect to purchases of Solodyn in Mississippi by members of the Class.
- m. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Mo. Rev. Stat. §§ 416.011, *et seq.*, with respect to purchases of Solodyn in Missouri by members of the Class.
- n. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Neb. Code Ann. §§ 59-802, *et seq.*, with respect to purchases of Solodyn in Nebraska by members of the Class.
- o. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Nev. Rev. Stat. Ann. §§ 598A.060, *et seq.*, with respect to purchases of Solodyn in Nevada by members of the Class.
- p. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of N.H. Rev. State. Ann. §§ 356, 356:2, 356:3, *et seq.*, with respect to purchases of Solodyn in New Hampshire by members of the Class.
- q. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of N.M. Stat. Ann. §§ 57-1-2, *et seq.*, with respect to purchases of Solodyn in New Mexico by members of the Class.

- r. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of New York General Business Law §§ 340, *et seq.*, with respect to purchases of Solodyn in New York by members of the Class.
- s. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of N.C. Gen. Stat. §§ 75-2.1, *et seq.*, with respect to purchases of Solodyn in North Carolina by members of the Class.
- t. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of N.D. Cent. Code §§ 51- 08.1-02, *et seq.*, with respect to purchases of Solodyn in North Dakota by members of the Class.
- u. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Or. Rev. Stat. §§ 646.705, *et seq.*, with respect to purchases of Solodyn Tablets in Oregon by members of the Indirect Purchaser Class.
- v. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of R.I. Chapter 6-36-7, *et seq.*, with respect to purchases of Solodyn in Rhode Island by members of the Class.
- w. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of S.D. Codified Laws Ann. §§ 37-1-3.2, *et seq.*, with respect to purchases of Solodyn in South Dakota by members of the Class.
- x. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Tenn. Code Ann. §§ 47-25- 101, *et seq.*, with respect to purchases of Solodyn in Tennessee by members of the Class.
- y. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Utah Code Ann. §§ 76-10-911, *et seq.*, with respect to purchases of Solodyn in Utah by members of the Class.
- z. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Vt. Stat. Ann. 9, §§ 2453, *et seq.*, with respect to purchases of Solodyn in Vermont by members of the Class.
- aa. Defendants have intentionally and wrongfully engaged in monopolization in the relevant markets in violation of W.Va. Code §§ 47-18-3, *et seq.*,



with respect to purchases of Solodyn in West Virginia by members of the Class.

- bb. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Wis. Stat. §§ 133.03, *et seq.*, with respect to purchases of Solodyn in Wisconsin by members of the Class.

**COUNT TWO: ATTEMPTED MONOPOLIZATION UNDER STATE LAW**  
**(Alleged against Defendant Medicis)**

244. Plaintiff refers to, and incorporates herein, the allegations found in the preceding paragraphs..

245. At all relevant times, Defendants possessed monopoly power in the relevant market.

246. Defendants manufactured the various formulations of Solodyn described herein. Defendants, *inter alia*, marketed and sold those various versions of Solodyn in the United States. During the relevant period, Defendants willfully and unlawfully maintained its monopoly power by engaging in exclusionary conduct that discouraged rather than encouraged competition on the merits.

247. The goal, purpose, and effect of Medicis' scheme was to delay and impair the sale of generic Solodyn products in the United States at prices significantly below Medicis' prices for Solodyn, thereby effectively preventing the average market price of extended-release minocycline hydrochloride products from declining dramatically.

248. Plaintiff and the End-Payor Class seek damages and multiple damages as permitted by law for their injuries by Defendants' violations of the following state antitrust laws:

- a. Defendants have intentionally and wrongfully engaged in attempted monopolization in the relevant market in violation of Arizona Rev. Stat. §§ 44- 1402, *et seq.*, with respect to purchases of Solodyn in Arizona by members of the Class.

- b. Defendants have intentionally and wrongfully engaged in attempted monopolization in the relevant market in violation of Cal. Bus. & Prof. Code §§ 16700, *et seq.*, with respect to purchases of Solodyn in California by members of the Class.
- c. Defendants have intentionally and wrongfully engaged in attempted monopolization in the relevant market in violation of D.C. Code §§ 28-4503, *et seq.*, with respect to purchases of Solodyn in the District of Columbia by members of the Class.
- d. Defendants have intentionally and wrongfully engaged in attempted monopolization in the relevant market in violation of Fla. Stat. §§ 501.201, *et seq.*, with respect to purchases of Solodyn in Florida by members of the Class.
- e. Defendants have intentionally and wrongfully engaged in attempted monopolization in the relevant market in violation of Hawaii Code §480, *et seq.*, with respect to purchases of Solodyn Tablets in Hawaii by members of the Indirect Purchaser Class.
- f. Defendants have intentionally and wrongfully engaged in attempted monopolization in the relevant market in violation of Iowa Code §§ 553, *et seq.*, with respect to purchases of Solodyn in Iowa by members of the Class.
- g. Defendants have intentionally and wrongfully engaged in attempted monopolization in the relevant market in violation of Kan. Stat. Ann. §§ 50-101, *et seq.*, with respect to purchases of Solodyn in Kansas by members of the Class.
- h. Defendants have intentionally and wrongfully engaged in attempted monopolization in the relevant market in violation of Me. Rev. Stat. Ann. 10, §§ 1102, *et seq.*, with respect to purchases of Solodyn in Maine by members of the Class.
- i. Defendants have intentionally and wrongfully engaged in attempted monopolization in the relevant market in violation of Mass. Ann. Laws. Ch. 93A, *et seq.*, with respect to purchases of Solodyn in Massachusetts by members of the Class.
- j. Defendants have intentionally and wrongfully engaged in attempted monopolization in the relevant market in violation of Mich. Comp. Laws Ann. §§ 445.772, *et seq.*, with respect to purchases of Solodyn in Michigan by members of the Class.

- k. Defendants have intentionally and wrongfully engaged in attempted monopolization in the relevant market in violation of Minn. Stat. §§ 325D.52, *et seq.*, and Minn. Stat. § 8.31, *et seq.*, with respect to purchases of Solodyn in Minnesota by members of the Class.
- l. Defendants have intentionally and wrongfully engaged in attempted monopolization in the relevant market in violation of Miss. Code Ann. §§ 75-21- 3, *et seq.*, with respect to purchases of Solodyn in Mississippi by members of the Class.
- m. Defendants have intentionally and wrongfully engaged in attempted monopolization in the relevant market in violation of Mo. Rev. Stat. §§ 416.011, *et seq.*, with respect to purchases of Solodyn in Missouri by members of the Class.
- n. Defendants have intentionally and wrongfully engaged in attempted monopolization in the relevant market in violation of Neb. Code Ann. §§ 59-802, *et seq.*, with respect to purchases of Solodyn in Nebraska by members of the Class.
- o. Defendants have intentionally and wrongfully engaged in attempted monopolization in the relevant market in violation of Nev. Rev. Stat. Ann. §§ 598A.060, *et seq.*, with respect to purchases of Solodyn in Nevada by members of the Class.
- p. Defendants have intentionally and wrongfully engaged in attempted monopolization in the relevant market in violation of N.H. Rev. State. Ann. §§ 356, 356:2, 356:3, *et seq.*, with respect to purchases of Solodyn in New Hampshire by members of the Class.
- q. Defendants have intentionally and wrongfully engaged in attempted monopolization in the relevant market in violation of N.M. Stat. Ann. §§ 57-1-2, *et seq.*, with respect to purchases of Solodyn in New Mexico by members of the Class.
- r. Defendants have intentionally and wrongfully engaged in attempted monopolization in the relevant market in violation of New York General Business Law §§ 340, *et seq.*, with respect to purchases of Solodyn in New York by members of the Class.
- s. Defendants have intentionally and wrongfully engaged in attempted monopolization in the relevant market in violation of N.C. Gen. Stat. §§ 75-2.1, *et seq.*, with respect to purchases of Solodyn in North Carolina by members of the Class.

- t. Defendants have intentionally and wrongfully engaged in attempted monopolization in the relevant market in violation of N.D. Cent. Code §§ 51- 08.1-02, *et seq.*, with respect to purchases of Solodyn in North Dakota by members of the Class.
- u. Defendants have intentionally and wrongfully engaged in attempted monopolization in the relevant market in violation of Or. Rev. Stat. §§ 646.705, *et seq.*, with respect to purchases of Solodyn Tablets in Oregon by members of the Indirect Purchaser Class.
- v. Defendants have intentionally and wrongfully engaged in attempted monopolization in the relevant market in violation of R.I. Chapter 6-36-7, *et seq.*, with respect to purchases of Solodyn in Rhode Island by members of the class.
- w. Defendants have intentionally and wrongfully engaged in attempted monopolization in the relevant market in violation of S.D. Codified Laws Ann. §§ 37-1-3.2, *et seq.*, with respect to purchases of Solodyn in South Dakota by members of the Class.
- x. Defendants have intentionally and wrongfully engaged in attempted monopolization in the relevant market in violation of Tenn. Code Ann. §§ 47-25- 101, *et seq.*, with respect to purchases of Solodyn in Tennessee by members of the Class.
- y. Defendants have intentionally and wrongfully engaged in attempted monopolization in the relevant market in violation of Utah Code Ann. §§ 76-10-911, *et seq.*, with respect to purchases of Solodyn in Utah by members of the Class.
- z. Defendants have intentionally and wrongfully engaged in attempted monopolization in the relevant market in violation of Vt. Stat. Ann. 9, §§ 2453, *et seq.*, with respect to purchases of Solodyn in Vermont by members of the Class.
- aa. Defendants have intentionally and wrongfully engaged in attempted monopolization in the relevant markets in violation of W.Va. Code §§ 47-18-3, *et seq.*, with respect to purchases of Solodyn in West Virginia by members of the Class.
- bb. Defendants have intentionally and wrongfully engaged in monopolization in the relevant market in violation of Wis. Stat. §§ 133.03, *et seq.*, with respect to purchases of Solodyn in Wisconsin by members of the Class. Plaintiff hereby incorporates paragraphs 1 through 242.

249. At all relevant times, Defendants possessed substantial market power (*i.e.*, monopoly power) in the relevant market. Defendants possessed the power to control prices in, prevent prices from falling in, and exclude competitors from the relevant market.

**COUNT THREE: CONSPIRACY TO MONOPOLIZE**  
**(alleged against all Defendants)**

250. Plaintiff refers to, and incorporates herein, the allegations found in the preceding paragraphs.

251. At all relevant times, Medicis possessed substantial market power, *i.e.*, monopoly power, in the relevant market. Medicis possessed the power to control prices in, prevent prices from falling in, and exclude competitors from the relevant market.

252. Through the overarching anticompetitive scheme, including the Exclusion Payment Agreements with Impax, Lupin, Sandoz, Mylan, Matrix, Teva, Ranbaxy, and Barr, Defendants knowingly and intentionally conspired to maintain and enhance Medicis' monopoly power in the relevant market by delaying and impairing market entry of generic Solodyn. The unlawful Exclusion Payment Agreements between Defendants allocated 100% or nearly 100% of the relevant market in the United States; delayed and impaired the sales of generic Solodyn products; and fixed the price at which consumers and other End-Payor Plaintiffs would pay at the higher, branded price.

253. The goal, purpose, and/or effect of the Exclusion Payment Agreements was to maintain and extend Medicis' monopoly power in the United States market for Solodyn and its generic equivalents. The Exclusion Payment Agreements prevented and/or delayed generic competition to Solodyn and enabled Medicis to continue charging supracompetitive prices for Solodyn without a loss of sales sufficient to make those prices unprofitable.

254. Defendants specifically intended that the Exclusion Payment Agreements would maintain Medicis' monopoly power in the relevant market, and injured Plaintiff and the Class thereby.

255. Defendants each committed at least one overt act in furtherance of the conspiracy.

256. As a direct and proximate result of Defendants' concerted conduct, as alleged herein, Plaintiff and the Class were harmed as aforesaid.

257. By engaging in the foregoing conduct, Defendants have violated the following state antitrust laws:

- a. Defendants have intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Arizona Rev. Stat. §§ 44-1402, *et seq.*, with respect to purchases of Solodyn and AB-rated bioequivalents in Arizona by members of the Class.
- b. Defendants have intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Cal. Bus. & Prof. Code §§ 16700, *et seq.*, with respect to purchases of Solodyn and AB-rated bioequivalents in California by members of the Class.
- c. Defendants have intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of D.C. Code §§ 28-4503, *et seq.*, with respect to purchases of Solodyn and AB-rated bioequivalents in the District of Columbia by members of the Class.
- d. Defendants have intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Fla. Stat. §§ 501.201, *et seq.*, with respect to purchases of Solodyn and AB-rated bioequivalents in Florida by members of the Class.
- e. Defendants have intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Iowa Code §§ 553, *et seq.*, with respect to purchases of Solodyn and AB-rated bioequivalents in Iowa by members of the Class.
- f. Defendants have intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Kan. Stat. Ann. §§ 50-101, *et seq.*, with respect to purchases of Solodyn and AB-rated bioequivalents in Kansas by members of the Class.

- g. Defendants have intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Me. Rev. Stat. Ann. 10, §§ 1102, *et seq.*, with respect to purchases of Solodyn and AB-rated bioequivalents in Maine by members of the Class.
- h. Defendants have intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Mass. Ann. Laws. Ch. 93A, *et seq.*, with respect to purchases of Solodyn and AB-rated bioequivalents in Massachusetts by members of the Class.
- i. Defendants have intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Mich. Comp. Laws Ann. §§ 445.772, *et seq.*, with respect to purchases of Solodyn and AB-rated bioequivalents in Michigan by members of the Class.
- j. Defendants have intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Minn. Stat. §§ 325D.52, *et seq.*, and Minn. Stat. § 8.31, *et seq.*, with respect to purchases of Solodyn and AB-rated bioequivalents in Minnesota by members of the Class.
- k. Defendants have intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Miss. Code Ann. §§ 75-21-3, *et seq.*, with respect to purchases of Solodyn and AB-rated bioequivalents in Mississippi by members of the Class.
- l. Defendants have intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Neb. Code Ann. §§ 59-802, *et seq.*, with respect to purchases of Solodyn and AB-rated bioequivalents in Nebraska by members of the Class.
- m. Defendants have intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Nev. Rev. Stat. Ann. §§ 598A.060, *et seq.*, with respect to purchases of Solodyn and AB-rated bioequivalents in Nevada by members of the Class.
- n. Defendants have intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of N.H. Rev. State. Ann. §§ 356, 356:2, 356:3, *et seq.*, with respect to purchases of Solodyn and AB-rated bioequivalents in New Hampshire by members of the Class.
- o. Defendants have intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of N.M. Stat. Ann. §§ 57-1-2, *et seq.*, with respect to purchases of Solodyn and AB-rated bioequivalents in New Mexico by members of the Class.
- p. Defendants have intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of New York General

Business Law §§ 340, *et seq.*, with respect to purchases of Solodyn and AB-rated bioequivalents in New York by members of the Class.

- q. Defendants have intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of N.C. Gen. Stat. §§ 75-2.1, *et seq.*, with respect to purchases of Solodyn and AB-rated bioequivalents in North Carolina by members of the Class.
- r. Defendants have intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of N.D. Cent. Code §§ 51-08.1-02, *et seq.*, with respect to purchases of Solodyn and AB-rated bioequivalents in North Dakota by members of the Class.
- s. Defendants have intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of 10 L.P.R.A. §§ 251, *et seq.*, with respect to purchases of Solodyn and AB-rated bioequivalents in Puerto Rico by members of the Class.
- t. Defendants have intentionally and wrongfully engaged in a conspiracy to monopolize in the relevant market in violation of R.I. Chapter 6-36-7, *et seq.*, with respect to purchases of Solodyn and AB-rated bioequivalents in Rhode Island by members of the Class.
- u. Defendants have intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of S.D. Codified Laws Ann. §§ 37-1-3.2, *et seq.*, with respect to purchases of Solodyn and AB-rated bioequivalents in South Dakota by members of the Class.
- v. Defendants have intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases of Solodyn and AB-rated bioequivalents in Tennessee by members of the Class.
- w. Defendants have intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Utah Code Ann. §§ 76-10-911, *et seq.*, with respect to purchases of Solodyn and AB-rated bioequivalents in Utah by members of the Class.
- x. Defendants have intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Vt. Stat. Ann. 9, §§ 2453, *et seq.*, with respect to purchases of Solodyn and AB-rated bioequivalents in Vermont by members of the Class.
- y. Defendants have intentionally and wrongfully engaged in a conspiracy to monopolize the relevant markets in violation of W.Va. Code §§ 47-18-3, *et seq.*, with respect to purchases of Solodyn and AB-rated bioequivalents in West Virginia by members of the Class.



- z. Defendants have intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Wis. Stat. §§ 133.03, *et seq.*, with respect to purchases of Solodyn and AB-rated bioequivalents in Wisconsin by members of the Class.

258. Plaintiff and members of the Class have been injured in their business or property by reason of Defendants' antitrust violations alleged in this Claim. Their injuries consist of: (1) being denied the opportunity to purchase lower-priced generic Solodyn products; and (2) paying higher prices for Solodyn products than they would have paid in the absence of Defendants' conduct. These injuries are of the type the laws of the above States, the District of Columbia, and Puerto Rico were designed to prevent, and flow from that which makes Defendants' conduct unlawful.

259. Plaintiff and the Class seek damages and multiple damages as permitted by law for their injuries resulting from Defendants' violations of the aforementioned statutes.

**COUNT FOUR: CONSPIRACY AND COMBINATION IN RESTRAINT OF TRADE**  
**UNDER STATE LAW**  
**(alleged against all Defendants)**

260. Plaintiff refers to, and incorporates herein, the allegations found in the preceding paragraphs.

261. By entering the Exclusion Payment Agreements, Medicis engineered an agreement with, between, and among the Generic Defendants not to compete with each other and to delay generic entry, which constituted a continuing illegal contract, combination, and conspiracy in restraint of trade.

262. In or about November 2008 and at times before the formal execution thereof, Medicis and Impax entered into the Medicis/Impax Exclusion Payment Agreement, a continuing illegal contract, combination, and conspiracy in restraint of trade under which Medicis agreed to make substantial payments to Impax in exchange for its agreement to delay bringing its generic

version of Solodyn to the market, the purpose and effect of which was to: (a) allocate to Medicis 100% or nearly 100% of the market for Solodyn and its generic equivalents in the United States; (b) delay or impair the sale of generic versions of Solodyn in the United States, thereby protecting Medicis from unrestrained generic competition; and (c) fix the price at which end-payors would pay for Solodyn and its generic equivalents at supracompetitive levels.

263. In or about March 2009 and at times before the formal execution thereof, Medicis and Teva entered into the Medicis/Teva Exclusion Payment Agreement, a continuing illegal contract, combination, and conspiracy in restraint of trade under which Medicis agreed to make substantial payments to Teva substantial in exchange for its agreement to delay bringing its generic version of Solodyn to the market, the purpose and effect of which was to: (a) allocate to Medicis 100% or nearly 100% of the market for Solodyn and its generic equivalents in the United States; (b) delay or impair the sale of generic versions of Solodyn in the United States, thereby protecting Medicis from unrestrained generic competition; and (c) fix the price at which end payors would pay for Solodyn and its generic equivalents at supracompetitive levels.

264. In or about February 2011 and at times before the formal execution thereof, Medicis and Teva entered into the Second Medicis/Teva Exclusion Payment Agreement, a continuing illegal contract, combination, and conspiracy in restraint of trade under which Medicis agreed to make substantial payments to Teva in exchange for its agreement to delay bringing its generic version of Solodyn to the market, the purpose and effect of which was to: (a) allocate to Medicis 100% or nearly 100% of the market for Solodyn and its generic equivalents in the United States; (b) delay or impair the sale of generic versions of Solodyn in the United States, thereby protecting Medicis from unrestrained generic competition; and (c) fix

the price at which end payors would pay for Solodyn and its generic equivalents at supracompetitive levels.

265. In or about August 2009 and at times before the formal execution thereof, Medicis and Sandoz entered into the Medicis/Sandoz Exclusion Payment Agreement, a continuing illegal contract, combination, and conspiracy in restraint of trade under which Medicis agreed to make substantial payments to Sandoz in exchange for its agreement to delay bringing its generic version of Solodyn to the market, the purpose and effect of which was to: (a) allocate to Medicis 100% or nearly 100% of the market for Solodyn and its generic equivalents in the United States; (b) delay or impair the sale of generic versions of Solodyn in the United States, thereby protecting Medicis from unrestrained generic competition; and (c) fix the price at which end-payors would pay for Solodyn and its generic equivalents at supracompetitive levels.

266. In or about July 2010 and at times before the formal execution thereof, Medicis and Mylan entered into the Medicis/Mylan Exclusion Payment Agreement, a continuing illegal contract, combination, and conspiracy in restraint of trade under which Medicis agreed to make substantial payments to Mylan in exchange for its agreement to delay bringing its generic version of Solodyn to the market, the purpose and effect of which was to: (a) allocate to Medicis 100% or nearly 100% of the market for Solodyn and its generic equivalents in the United States; (b) delay or impair the sale of generic versions of Solodyn in the United States, thereby protecting Medicis from unrestrained generic competition; and (c) fix the price at which end-payors would pay for Solodyn and its generic equivalents at supracompetitive levels.

267. In or about May 2010 and at times before the formal execution thereof, Medicis and Ranbaxy entered into the Medicis/Ranbaxy Exclusion Payment Agreement, a continuing illegal contract, combination, and conspiracy in restraint of trade under which

Medicis agreed to make substantial payments to Mylan in exchange for its agreement to delay bringing its generic version of Solodyn to the market, the purpose and effect of which was to: (a) allocate to Medicis 100% or nearly 100% of the market for Solodyn and its generic equivalents in the United States; (b) delay or impair the sale of generic versions of Solodyn in the United States, thereby protecting Medicis from unrestrained generic competition; and (c) fix the price at which end-payors would pay for Solodyn and its generic equivalents at supracompetitive levels.

268. In or about July 2011 and at times before the formal execution thereof, Medicis and Lupin entered into the Medicis/Lupin Exclusion Payment Agreement, a continuing illegal contract, combination, and conspiracy in restraint of trade under which Medicis agreed to make substantial payments to Lupin in exchange for its agreement to delay bringing its generic version of Solodyn to the market, the purpose and effect of which was to: (a) allocate to Medicis 100% or nearly 100% of the market for Solodyn and its generic equivalents in the United States; (b) delay or impair the sale of generic versions of Solodyn in the United States, thereby protecting Medicis from unrestrained generic competition; and (c) fix the price at which end-payors would pay for Solodyn and its generic equivalents at supracompetitive levels.

269. The Exclusion Payment Agreements covered a sufficiently substantial percentage of the relevant market to harm competition.

270. As a direct and proximate result of Defendants' unlawful restraint of trade and unlawful maintenance of and conspiracy to maintain Medicis' monopoly power, Plaintiff and members of the Class paid artificially inflated prices for Solodyn and its generic equivalents as described herein, and were harmed as a result.

271. The purpose and effect of the payments flowing from Medicis to Generic Defendants under the Agreements was to delay and impair generic competition to Solodyn, and there is no legitimate, non-pretextual, pro-competitive business justification for the Exclusion Payments that outweighs their harmful effects.

272. By engaging in the foregoing conduct, Defendants have intentionally and wrongfully engaged in one or more combinations and conspiracies in restraint of trade in violation of the following state laws:

- a. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Arizona Rev. Stat. §§ 44-1401, *et seq.*, with respect to purchases of Solodyn and AB-rated generic equivalents in Arizona by members of the Class.
- b. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Cal. Bus. Code §§ 16700, *et seq.*, and Code §§ 17200, *et seq.*, with respect to purchases of Solodyn and AB-rated generic equivalents in California by members of the Class.
- c. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of D.C. Code Ann. §§ 28-45031, *et seq.*, with respect to purchases of Solodyn and AB-rated generic equivalents in the District of Columbia by members of the Class.
- d. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Fla. Stat. §§ 501. Part II, *et seq.*, with respect to purchases of Solodyn and AB-rated generic equivalents in Florida by members of the Class, and this conduct constitutes a predicate act under the Florida Deceptive Practices Act.
- e. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Kan. Stat. Ann. §§ 50-101, *et seq.*, with respect to purchases of Solodyn and AB-rated generic equivalents in Kansas by members of the Class.
- f. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Me. Rev. Stat. Ann. 10, § 1101, *et seq.*, with respect to purchases of Solodyn and AB-rated generic equivalents in Maine by members of the Class.

- g. Defendant have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Mass. Ann. Laws ch. 93, *et seq.*, with respect to purchases of Solodyn and AB-rated generic equivalents in Massachusetts by members of the Class.
- h. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Mich. Comp. Laws Ann. §§ 445.771, *et seq.*, with respect to purchases of Solodyn and AB-rated generic equivalents in Michigan by members of the Class.
- i. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Minn. Stat. §§ 325D.52, *et seq.*, with respect to purchases of Solodyn and AB-rated generic equivalents in Minnesota by members of the Class.
- j. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Miss. Code Ann. §§ 75-21-1, *et seq.*, with respect to purchases of Solodyn and AB-rated generic equivalents in Mississippi by members of the Class.
- k. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Neb. Code Ann. §§ 59-801, *et seq.*, with respect to purchases of Solodyn and AB-rated generic equivalents in Nebraska by members of the Class.
- l. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Nev. Rev. Stat. Ann. § 598A, *et seq.*, with respect to purchases of Solodyn and AB-rated generic equivalents in Nevada by members of the Class, in that thousands of sales of Solodyn took place at Nevada pharmacies, purchased by Nevada end-payers at supracompetitive prices caused by Defendants' conduct.
- m. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of N.M. Stat. Ann. §§ 57-1-1, *et seq.*, with respect to purchases of Solodyn and AB-rated generic equivalents in New Mexico by members of the Class.
- n. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of New York General Business Law § 340, *et seq.*, with respect to purchases of Solodyn and AB-rated generic equivalents in New York by members of the Class.
- o. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of N.C. Gen. Stat. §§ 75-1, *et seq.*, with respect to purchases of Solodyn and AB-rated generic

equivalents in North Carolina by members of the Class.

- p. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of N.D. Cent. Code § 51-08.1-01, *et seq.*, with respect to purchases of Solodyn and AB-rated generic equivalents in North Dakota by members of the Class.
- q. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Or. Rev. Stat. §§ 646.705, *et seq.*, with respect to purchases of Solodyn and AB-rated generic equivalents in Oregon by members of the Class.
- r. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of 10 L.P.R.A. § 258 with respect to purchases of Solodyn and AB-rated generic equivalents in Puerto Rico by members of the Class.
- s. Defendants have intentionally and wrongfully engaged in a combination or conspiracy in restraint of trade in violation of R.I. Chapter 6-36-7, *et seq.*, with respect to purchases of Solodyn in Rhode Island by members of the Class.
- t. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of S.D. Codified Laws Ann. § 37-1, *et seq.*, with respect to purchases of Solodyn and AB-rated generic equivalents in South Dakota by members of the Class.
- u. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases of Solodyn and AB-rated generic equivalents in Tennessee by members of the Class, in that the actions and transactions alleged herein substantially affected Tennessee, with thousands of end-payors in Tennessee paying substantially higher prices for Solodyn and AB-rated generic equivalents at Tennessee pharmacies.
- v. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Utah Code Ann. §§ 76-10-911, *et seq.*, with respect to purchases of Solodyn and AB-rated generic equivalents in Utah by members of the Class.
- w. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Vt. Stat. Ann. 9, § 2453, *et seq.*, with respect to purchases of Solodyn and AB-rated generic equivalents in Vermont by members of the Class.

- x. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of W.Va. Code §§ 47-18-1, *et seq.*, with respect to purchases of Solodyn and AB-rated generic equivalents in West Virginia by members of the Class.
- y. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Wis. Stat. § 133.01, *et seq.*, with respect to purchases of Solodyn and AB-rated generic equivalents in Wisconsin by members of the Class, in that the actions and transactions alleged herein substantially affected the people of Wisconsin, with thousands of end-payors in Wisconsin paying substantially higher price for Solodyn at Wisconsin pharmacies.

273. Plaintiff and members of the Class have been injured in their business or property by reason of Defendants' antitrust violations alleged in this Claim. Their injuries consist of: (1) being denied the opportunity to purchase lower-priced generic Solodyn, and (2) paying higher prices for branded Solodyn than they otherwise would have paid in the absence of Defendants' conduct. These injuries are of the type the laws of the above States, the District of Columbia and Puerto Rico were designed to prevent, and flow from that which makes Defendants' conduct unlawful.

274. Plaintiff and the Class seek damages and multiple damages as permitted by law for their injuries by Defendants' violations of the aforementioned statutes.

**COUNT FIVE: UNJUST ENRICHMENT**  
**(Alleged against all Defendants)**

275. Plaintiff incorporates by reference each of the preceding paragraphs.

276. Defendants have benefited from the monopoly profits on the sale of Solodyn resulting from the unlawful and inequitable acts alleged in this Complaint.

277. Defendants' financial benefit resulting from unlawful and inequitable conduct is traceable to overpayments for Solodyn by Plaintiff and members of the Class.



278. Plaintiff and the Class have conferred upon Defendants an economic benefit, in the nature of profits resulting from unlawful overcharges and monopoly profits, to the economic detriment of Plaintiff and the Class.

279. It would be futile for Plaintiff and the Class to seek a remedy from any party with whom they had privity of contract.

280. It would be futile for Plaintiff and the Class to seek to exhaust any remedy against the immediate intermediary in the chain of distribution from which it indirectly purchased Solodyn, as they are not liable and would not compensate Plaintiff for unlawful conduct caused by Defendants.

281. The economic benefit of overcharges and unlawful monopoly profits derived by Defendants through charging supracompetitive and artificially inflated prices for Solodyn is a direct and proximate result of Defendants' unlawful practices.

282. The financial benefits derived by Defendants rightfully belong to Plaintiff and the Class, as Plaintiff and the Class paid anticompetitive and monopolistic prices during the Class Period, inuring to the benefit of Defendants.

283. It would be inequitable under unjust enrichment principles in the District of Columbia and each of the fifty states, except for Ohio and Indiana, for Defendants to be permitted to retain any of the overcharges for Solodyn derived from Defendants' unfair and unconscionable methods, acts, and trade practices alleged in this complaint.

284. Defendants are aware of and appreciates the benefits bestowed upon it by Plaintiff and the Class.

285. Defendants should be compelled to disgorge in a common fund for the benefit of Plaintiff and the Class all unlawful or inequitable proceeds it received.

286. A constructive trust should be imposed upon all unlawful or inequitable sums received by Defendants traceable to Plaintiff and the Class.

287. Plaintiff and the Class have no adequate remedy at law.

**COUNT SIX:**  
**(DECLARATORY AND INJUNCTIVE RELIEF UNDER**  
**SECTION 16 OF THE CLAYTON ACT FOR DEFENDANTS'**  
**VIOLATIONS OF SECTIONS 1 AND 2 OF THE SHERMAN ACT)**  
**(Asserted against All Defendants)**

288. Plaintiff incorporates by reference each of the preceding paragraphs.

289. Plaintiff's allegations described herein and in Claims I through VI comprise violations of Sections 1 and 2 of the Sherman Act, as well as the state laws *supra*.

290. Plaintiff and the Class, pursuant to Fed. R. Civ. P. 57 and 28 U.S.C. § 2201(a), hereby seek a declaratory judgment that Defendants' conduct in seeking to prevent competition as described herein violates Sections 1 and 2 of the Sherman Act.

291. Plaintiff and the Class further seek equitable and injunctive relief pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26, and other applicable law, to correct for the anticompetitive market effects caused by the unlawful conduct of Defendants, and other relief so as to assure that similar anticompetitive conduct does not reoccur in the future.

**X. PRAYER FOR RELIEF**

292. WHEREFORE, Plaintiff, on behalf of itself and the Class, respectfully prays that:

A. The Court determine that this action may be maintained as a class action pursuant to Rule 23(a), (b)(2) and (b)(3) of the Federal Rules of Civil Procedure, and direct that reasonable notice of this action, as provided by Rule 23(c)(2) of the Federal Rules of Procedure, be given to the Class, and declare the Plaintiff as the representative of the Indirect Purchaser Class;

B. The acts alleged herein be adjudged and decreed to be in violation of state antitrust, consumer protection, and unjust enrichment laws as alleged herein;

C. Enter joint and several judgments against Defendants and in favor of Plaintiff and the Indirect Purchaser Class.

D. Permanently enjoin the Defendants pursuant to sections 4 and 16 of the Clayton Act, 15 U.S.C. §§15(a) and 26, from continuing their unlawful contact, so as to assure that similar anticompetitive conduct does not continue to occur in the future;

E. Award the Indirect Purchaser Class damages (*i.e.*, three times overcharges) in an amount to be determined at trial;

F. Award Plaintiff and the Indirect Purchaser Class equitable relief in the nature of disgorgement, restitution, and the creation of a construction trust to remedy Defendants' unjust enrichment;

G. Award Plaintiff and the Indirect Purchaser Class damages as permitted by law, including disgorgement;

H. Award Plaintiff and the Indirect Purchaser Class their costs of suit, including reasonable attorneys' fees as provided by law; and

I. Such other and further relief as the Court may deem just and proper.

#### **XI. JURY TRIAL DEMANDED**

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiff demands a trial by jury of all claims and complaints in this Complaint so triable.

Dated: October 2, 2013

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